University of Alberta

Social and Behavioural Correlates of Glycemic Control

by

Chad Gordon Mitchell ©

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of the requirements for the degree of Master of Science.

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The undersigned certify that they have read, and recommend to the Faculty of Graduate Studies and Research for acceptance, a thesis entitled Social and Behavioural Correlates of Glycemic Control submitted by Chad Gordon Mitchell in partial fulfillment of the requirements for the degree of Master of Science in Pharmacy and Pharmaceutical Sciences.

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Abstract

The aim of this study was to investigate the relationship between glycemic control, frequency of blood sugar testing and social or behavioural characteristics and attempt to contrast these relationships for those with insurance that covers self-monitoring of blood glucose (SMBG) testing supplies to those without insurance that covers SMBG testing supplies.

This was a cross-sectional study that utilized the baseline data from the first 200 patients that completed a survey and blood work for enrollment into a prospective, randomized, control trial.

Overall, this study demonstrated little relationship between glycemic control, frequency of blood sugar testing and social or behavioural characteristics of people with type 2 diabetes. There was a clinically significant difference in HbA1c (0.37%; $p<0.05$) between those who had insurance that covered BG testing strips and those who did not. Further research into SMBG would be required in order to make informed policy decisions.

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Chapter 1

Introduction

1.1 Statement of the Problem

Diabetes mellitus (DM) is recognized as a public health problem of potentially enormous proportions (Health Canada, 1999; Canadian Diabetes Association, 2001; Meltzer et al., 1998). It is estimated that approximately 2 million Canadians, or about 5% of the Canadian population (Meltzer et al., 1998), have diabetes and that number is expected to reach 3 million by 2010 (Canadian Diabetes Association, 2001). Approximately 10 per cent of individuals with diabetes have type 1 diabetes (Canadian Diabetes Association, 2000); the remaining 90 per cent are affected by type 2 diabetes (Campbell et al., 2000). A third type of diabetes, gestational diabetes, is a temporary condition that occurs during pregnancy.

The primary metabolic abnormality in DM is high blood glucose (BG) concentration resulting from deficient insulin production or action (Coster et al., 2000, Meltzer et al., 1998). Type 2 DM has been recognized as a silent killing disease, where cardiovascular disease (CVD) is the principle cause of death for about 70 percent of patients (Campbell et al., 2000). Accelerating atherosclerosis may be present for many years before the onset of clinical diabetes. Other potential long term complications for persons with diabetes include blindness, renal failure, and lower extremity amputations (Harris et al., 2000).

These end stage complications result only after a long duration of diabetes (Williams R, 2002). The disease often disables people in their middle years and, as a group, people with diabetes die younger than those not affected by it (Meltzer et al., 1998). The life expectancy of a type 2 DM patient is reduced by between 30 and 40 percent for those in the age range of 40-70 years, a loss of eight to ten years of life (Campbell et al., 2000).

The focus of diabetes treatment has been the establishment of optimum metabolic control, while controlling for comorbidities such as hypertension and dyslipidemias. Optimal metabolic control for a person with diabetes is often sought through a triad of therapies that includes diet, medication, and exercise (Coster et al., 2000; Meltzer et al., 1998; Jones et al., 1996; Peragallo-Dittko et al., 1993). Daily assessment of metabolic control can be achieved through self-monitoring of blood glucose (SMBG).

For those with type 1 diabetes, evidence for self-monitoring of blood glucose within a complete package of intensive DM management is demonstrated in the Diabetes Control and Complication Trial (DCCT) (Coster et al., 2000). SMBG is considered an essential component of management of type 1 DM in the current clinical practice guidelines from the Canadian Diabetes Association (CDA-CPG) (Meltzer et al., 1998).

The importance of strict glycemic control in the type 2 population has been demonstrated in a recent clinical trial. The United Kingdom Prospective Diabetes Study concluded that individuals with type 2 diabetes benefit from tight glycemic controls, which applies to those in any diabetic blood sugar range (Stratton et al., 2000). Not only does the intensive glycemic control decrease morbidity in type 2 diabetes, but also significant savings from the reduction costs of complications can be achieved (Gray et al., 2000).

SMBG is used to measure glucose levels in the blood stream and has markedly improved the ability to control glucose levels (Meltzer et al., 1998; Goldstein et al., 1997). Results of this monitoring may be used to correct deviations in glucose levels (Wagner et al., 1998; Meltzer et al., 1998). Although the monitoring does not in itself alter blood glucose levels, it provides the information essential to adjust the regimen and bring glucose levels under control (Wagner et al., 1998). This is especially beneficial in type 1 DM where daily excursions of hyperglycemia and hypoglycemia may be common (Coster et al., 2000).

Despite the importance of strict glycemic control in type 2 diabetes, SMBG has been suggested to be unnecessary (Coster et al., 2000) and perhaps a waste of resources (Gallichan, 1997). Overall, in the available literature, there is conflicting research evidence to support most recommendations for SMBG in type 2 diabetes (Franciosi et al., 2001; Coster et al., 2000; Crossland NJ, 1997; Strachan MWJ et al., 1997; Chantelau & Nowicki, 1997). While this conclusion seems counter to generally accepted clinical practice and treatment guidelines, it is not clear from the literature what the impact of SMBG alone is. This is not to say that there is no beneficial effect of SMBG, but that there is little research evidence to support it (Coster et al., 2000).

The total annual cost of DM in Canada has been estimated to be at $9 billion U.S. dollars (Canadian Diabetes Association, 2000). In 1995, £42.6 million (£1 approximately $2.50 CDN) was spent on home monitoring of glucose in the United Kingdom (Gallichan, 1997). In 2001, the market for blood glucose monitors approximated $2.0 billion (U.S.) in the United States (Woo, 2001; Kaster, 2002). With the population of Canada being roughly 1/10th the size of the U.S., we could approximate the Canadian market for home blood glucose monitoring to be approximately $200 million U.S. It has been anticipated by that the market will grow 12-15% over the next several years (Kaster, 2002).

There is very little evidence of the cost of SMBG. Using administrative data from Saskatchewan Health we recently estimated the mean total cost for diabetes testing supplies per beneficiary with dispensation claims for testing supplies was $241 in 1996 (Mitchell et al, 2002). The mean annual cost of testing strips per person with type 2 diabetes not using insulin was $159 (SD $165) for those on oral hypoglycemic agents alone, and $116 (SD $118) for those not on any medication for their diabetes. We found that diabetes testing strips accounted for approximately 12.5% of the total costs of SPDP claims for individuals identified as having diabetes.

Despite the lack of supporting evidence and costs associated with the practice, the use of SMBG in type 2 DM has become well established in clinical practice (Coster et al., 2000, Goldstein et al., 1997). However, it has been reported that low levels of adherence to SMBG (Jones 1996, Woo 2001; Wagner 1998; Evans et al., 1999; Nyomba et al., 2002) continue to occur despite its establishment. From our Saskatchewan Health data, it was estimated that in 1996 less than one half of the people diagnosed with diabetes had a dispensation for blood glucose test strips (Mitchell et al., 2002). We also observed that approximately 74% of people on insulin had dispensations for diabetes testing strips. For those that were on oral hypoglycemic agents alone, approximately 50% had dispensations for SMBG test strips. Only approximately 15% of patients that controlled their diabetes with diet alone had dispensations for diabetes test strips.

A potential problem in adherence to SMBG might lie in the position that there is no clear understanding of the role of SMBG (ADA, 2002) specifically among those who have type 2 diabetes and are treated by diet alone or oral hypoglycemic agents. Both the CDA-CPG (Meltzer et al., 1998) and American guidelines (ADA, 2002) for diabetes care make no specific recommendations on frequency of SMBG for those patients with diabetes and not on insulin. Individuals and health care practitioners are left to assess the frequency of SMBG in order to achieve BG goals. Other factors that could affect SMBG practices include barriers in convenience, cost, and self-efficacy judgments about SMBG (Nyomba et al., 2002, Aljasem et al., 2001; Glasgow et al., 1997 Irvine et al., 1990).

1.2 Purpose

The aim of this study was to investigate the relationship between diabetes self-care activities, barriers to care, health-related quality of life (HRQOL), and glycemic control and attempt to contrast these relationships for those with insurance that covers SMBG testing supplies to those without insurance that covers SMBG testing supplies.

1.2.1 Hypotheses

Hypothesis that are addressed in this thesis include:

1) Subjects with low adherence to SMBG will have poorer glycemic control, as measured by HbA1c.

2) Subjects with greater fear of hypoglycemia will have poorer glycemic control, as measured by HbA1c.

3) Subjects with worse self-reported health status will have poorer glycemic control, as measured by HbA1c.

4) Subjects with greater self-perceived barriers to SMBG testing will have poorer glycemic control, as measured by HbA1c.

5) There is no difference in relationship of self-reported frequency of SMBG and environmental barriers to glucose testing while controlling for HbA1c

6) There are no differences in the relationship between the dependent variable (DV) and the independent variable (IV) in hypotheses one through four between those with insurance that covers SMBG test strips and those without insurance that covers SMBG test strips.

1.3 Significance of the study

Identification of factors influencing self-care behaviors is a major theme in diabetes patient-education research (Irvine et al., 1990). Educating patients in techniques of self-care is important in achieving treatment objective (Coster et al., 2000). Relatively little is known about the current practice patterns, and barriers associated with SMBG (Karter et al., 2000). Potential barriers to diabetes care include the high cost of SMBG supplies, patient discomfort and inconvenience with SMBG, dietary adherence, and exercise (Karter et al., 2000; Glasgow et al., 1997). These self-care activities and perceived barriers have been studied separately (Toobert et al., 2000; Karter et al., 2000; Ruggiero et al., 1997; Irvine et al., 1990), however, the relationship between these activities has not yet been studied.

There is weakness in the recommendations in SMBG for those not on insulin therapy for DM. There are also concerns about the availability of resources to achieve strict glycemic control in the general diabetic population (Gallichan, 1997; Goldstein et al., 1997; Coster et al., 2000; Karter et al., 2000) The use of SMBG could also be perceived to be a costly intervention, with the market for SMBG supplies expected to grow at an annual rate of 12-15%. For those individuals with a lack of insurance, SMBG is either paid for out of pocket or not adhered. For health benefit managers or health ministries the evidence on which to base a policy decision that covers the cost of SMBG testing supplies for people with type 2 diabetes is lacking. This study will expand the knowledge of SMBG in this group of people with diabetes.

Chapter 2

Review of the Literature

2.1 Diabetes and Glycemic Control

The importance of strict glycemic control for those with type 1 and type 2 DM has been demonstrated in clinical trials (DCCT, 1993; Gray et al., 2000). This chapter will first briefly review the literature on the clinical, economic and HRQOL in type 1 and type 2 DM. Next, self-care activities for those with type 2 DM will be presented. Methods of monitoring blood glucose and literature on SMBG for those with type 1 and type 2 DM will be briefly addressed. Lastly, selective literature on the barriers to self-monitoring of blood glucose will be presented.

2.1 Clinical

2.1.1 Type 1 DM

The Diabetes Control and Complications Trial (DCCT) was a multicenter, randomized clinical trial that demonstrated that intensive therapy of patients with type 1 diabetes delays the onset and slows the progression of clinically important retinopathy, nephropathy, and neuropathy (DCCT 1993). The intensive therapy regimen was designed to achieve blood glucose values as close to normal as possible with three or more daily insulin injections or treatment with an insulin pump. Conventional therapy consisted of one or two insulin injections per day. The intensive treatment group in addition to comprehensive education and follow-up by a diabetes team, adjusted insulin daily based on the results of SMBG, while the conventional group preformed SMBG, daily adjustment of insulin was usually not included in the regimen. A total of 1441 patients were recruited between 1983 through 1989.

A statistically significant difference in the average glycated hemoglobin value was maintained after based line between the intensive-therapy and conventional-therapy in both cohorts ($p<0.001$). The mean value for all glucose profiles in the intensive group was 8.6mmol/l (SD 1.7), as compared with 12.8mmol/l (SD 3.1) in the conventional group ($p<0.001$). In a primary prevention cohort, intensive therapy reduced the adjusted mean risk of progression of retinopathy by 76 percent as compared with conventional therapy ($p<0.001$). The intensive therapy group also reduced the risk of microalbinuria by 34 percent ($p = 0.04$).

The incidence of severe hypoglycemia, including multiple episodes in some patients, was approximately three times higher in the intensive group than in the conventional ($p<0.001$) (DCCT, 1993; DCCT, 1991). Despite the higher risk of hypoglycemia in the intensive group, there was no difference between the two therapy groups in the occurrence of clinically important changes in neuropsychological function (Reichard et al., 1993; DCCT, 1993). There were no deaths, myocardial infarctions, or strokes definitely attainable to hypoglycemia, and no significant differences between groups with regard to the number of major accidents requiring hospitalization (DCCT, 1993).

2.1.2 Type 2 DM

The importance of strict glycemic control in the type 2 population has been demonstrated in the United Kingdom Prospective Diabetes Study (UKPDS). Results from the UKPDS suggested that not only those individuals with type 2 DM and high blood sugars benefit from tight glycemic controls, but this also applies to those in any diabetic blood sugar range (Stratton et al., 2000).

The UKPDS added to our knowledge that with each 1% reduction in HbA1c was associated with a 37% decrease in the risk for microvascular complications and a 21% decrease in the risk of any endpoint or death related for diabetes. However, for stroke, heart failure, and myocardial infarction the association with glycaemia was less steep, with no significant decrease in risk seen for a 1% decrease in HbA1c.

While there was no direct relationship between HbA1c reduction and cardiovascular endpoints, the data from the UKPDS suggest that the effect of hyperglycemia itself may account for at least a part of the excess risk observed in people with diabetes, compared with non-diabetic people beyond that explained by the conventional risk factors of dyslipidaemia, hypertension, and smoking (Stratton et al., 2000).

The relation between glycaemia and outcome is complex, but the UKPDS has shown that improved glucose control reduces the risk of the diabetic complication that cause morbidity and suggest the mechanisms by which this might occur (Gray et al., 2000). Although the UKPDS did not directly establish any effect of lowering blood glucose on cardiovascular complications, the use of insulin, sulfonylureas, or metformin (and perhaps metformin in combination with sulfonylureas) does not appear to increase the risk of cardiovascular events (ADA., 2002).

2.2 Economic Considerations

2.2.1 Type 1 DM

The total economic burden of diabetes in Canada has been estimated at between $4.76 and $5.23 billion (U.S. dollars) in 1998 (Dawson et al., 2002). This estimate included both the direct medical costs for individuals with diabetes and the cost of mortality-related productivity losses due to the diseases. Direct medical costs were approximately $2.6 billion or 7.8% of the total medical expenditures in Canada during 1998. Cardiovascular disease, including peripheral vascular disease, accounted for ~35% of the total burden of diabetes.

In the DCCT, the cost of intensive therapy was two to three times greater than that of conventional therapy (Herman and Eastman, 1998; DCCT, 1995). A large portion of the difference in cost was related to the greater frequency of outpatient visits and the greater resources used in self-care (Table 2.1)(Herman et al., 1997). With respect to the outpatient costs, people receiving intensive therapy were seen by a physician 12 times per year, verses people on conventional treatment had 4 outpatient consultations per year. The greater costs for self-care among those receiving intensive therapy were primarily due to the increased requirement for SMBG. Patients receiving intensive treatment used SMBG an average of 1460 tests per year versus 267 test per year for those who were in the conventional therapy group. The 150% increase in costs for continuous subcutaneous insulin infusion (CSII) compared with multiple daily injections (MDI) was almost entirely due to the costs of the insulin pumps and pump related supplies.

Table 2.1 Annual Costs of intensive and conventional therapy in the DCCT.

Service	MDI	CSII	Conventional
Inpatient	$127	$155	$58
Outpatient	$1243	$1244	$513
Case Management	$548	$554	$116
Self-care	$1886	$3621	$909
Side Effects	$210	$210	$70
Total	**$4014**	**$5784**	**$1666**

(Herman et al., 1997)

The benefit of tight glycemic control in the intensive therapy group was shown to be cost-effective relative to conventional therapy, but intensive therapy is not cost-saving. Using a 3% discount rate, the expected lifetime cost per patient was $99,822 for intensive therapy and $66,076 for conventional therapy (Herman et al., 1997). On average, intensive therapy cost $33,746 more than conventional therapy per patient over a lifetime. When benefits and cost were discounted at 3% per year, the incremental cost per QALY (Quality Adjusted Life Year) gained was $19,987.

2.2.2 Type 2 DM

Using a Monte Carlo modeling technique, Caro et al., estimated the costs of complications from type 2 diabetes in the U.S. population (Caro et al., 2002). Patients who had type 2 diabetes for 5 years before entering the model with an average HbA1c of 8.4%, which then increases an average of 0.15% per year are expected to accrue, on average, $47,240 for managing complications over 30 years. The management of macrovascular disease was estimated to be the largest cost component costing about 52% of the overall costs. Nephropathy accounts for 21%, neuropathy accounts for 17%, and retinopathy accounts for 10%.

Intensive treatment has been shown to significantly offset the costs of treating complications of diabetes (Gray et al., 2000). Using the UKPDS trial information, Gray and coworkers demonstrated that an intensive policy increased the trial costs by 695 pounds per patient. If standard practice visit patterns were assumed rather than trial conditions, the incremental cost of intensive management was 478 pounds. However, these costs were offset by the reduction in the cost of complications by 957 pounds compare with conventional management.

The objective of an article written by Klonoff and Schwartz (Klonoff & Schartz, 2000) was to stratify interventions for diabetes according to their economic impact. Reviewing literature that preformed a cost-benefit analysis, the authors classified the economic impact for individual interventions as 1) clearly cost-saving, 2) clearly cost-effective, 3) possible cost-effective, 4) non-cost-effective, or 5) unclear. Clearly cost effective interventions included nephropathy prevention in type 1 diabetes and improved glycemic control. Possibly cost-effective interventions included nephropathy prevention in type 2 diabetes and self-management training. SMBG was included among the interventions cited as having an unclear relationship between the medical and economic benefits.

2.3 Health Related Quality of Life.

2.3.1 Type 1 DM

The DCCT collected HRQL data during the annual patient visits (DCCT, 1996). All analyses of HRQL, psychiatric symptom indexes, and psychosocial event data showed no differences between intensive and conventional diabetes treatment. It found that people undergoing intensive treatment did not experience deterioration in the quality of their lives, even while the rigor of their diabetes care was increased (Herman, 1999). The occurrence of severe hypoglycemia was not consistently associated with a subsequent increase in distress due to symptoms or decline in diabetes related quality of life. However, in the primary prevention intensive treatment group, people who had repeated severe hypoglycemia (three or more events resulting in coma or seizure) tended to be at increased risk of measurable distress due to symptoms.

2.3.2 Type 2 DM

The UKPDS has shown that a policy to improve glucose control in type 2 diabetes with more intensive management reduce the risk for diabetes related complications. Complications of the disease affected quality of life, whereas therapeutic policies shown to reduce the risk of complications had no effect on quality of life (UKPDS, 1999). Multivariate analysis, that allowed for characteristics associated with complications, such as HbA1c, did not materially change the results. Macrovascular complications were associated with significantly worse general health, more problems with usual mobility and usual activities, and less vigor. Microvascular complications were significantly associated with more reported tension and total mood disturbance.

2.3.3 Health related quality of life and HbA1c

Health-related quality of life (HRQOL) can be defined as optimal levels of mental, physical, role (e.g. work, parent, career, ect.) and social functioning, including relationships, perceptions of health, fitness, life satisfaction and well-being (Bowling, 1995). The use of HRQOL measurements enables a researcher to measure the multidimensional nature of health (Anderson, 1997). These outcomes measurements are particularly important in chronic diseases in which, despite the impossibility of cure, patients often are asked to undertake complex, expensive, and intrusive therapeutic regimens (Weinberger et al., 1994).

Because self-rated health is regarded as an important outcome of the care of people with type 2 diabetes, it is important to attempt to quantify the relative importance of factors that influence HRQOL (Klein et al., 1998; Jacobson AM et al., 1994). The use of HRQOL measurements to describe the effects of DM are in a growing body of literature (Luscombe et al., 2000; Wandell PE et al., 2000; Johnson et al., 1998; Jacobson AM, 1997). HRQOL scores have been compared between those with diabetes and those with another disease state and/or in the general population (de Visser et al., 2002; Wandell PE et al., 2000; Johnson et al., 1998; Hermann et al., 1996). Behavioral/therapeutic interventions (Ahroni et al., 2000; Testa et al., 1998) also use HRQOL to show the effects of interventions on clinical outcomes, specifically HbA1c (Hanninen et al., 2001; Franciosi et al., 2001) However, generic HRQOL measures and their associations with HbA1c have not been clear with previous studies not confirming the relation between greater HbA1c and worse HRQL (Wandell & Tovi, 2000; UKPDS, 1999; Klein et al., 1998; Testa MA et al., 1998).

Anderson and co-workers (1997) compared generic and (diabetes) disease specific measures. The SF-36 was compared with the disease specific Diabetes Care Profile (DCP) in the same population of both insulin and non-insulin dependant type 2 diabetic patients. For patients not using insulin, the DCP correlated with all nine of the SF-36 subscales. Those on insulin, the DCP correlated with six of the SF-36 subscales. The SF-36 was found not to have the predictive validity related to glycemic control, were as; the DCP was able to explain 15-17% of the variance in glycemic controls.

Multivariate regression modeling using baseline and change scores over a 1-year period did not find any linear nor curvilinear relationship between glycated hemoglobin and SF-36 scores (Weinberger et al., 1994). Pearson's correlation coefficients of glycemic control with SF-36 subscales were found to range from –0.09 to –0.04. Weinberger et al. concluded that improvements in glycemic control may be exceedingly difficult to achieve, and following complex regimens that are required for improvement is as likely to diminish HRQOL. A second interpretation was that lifestyle changes required to improve glycemic control did not adversely affect patients' HRQOL. Finally, complications that affect HRQOL do not occur immediately.

In a cross-sectional study done by Jackobson and coworkers (1994), the DQOL and SF-36 were compared. Internal consistency of the DQOL with type 2 persons with diabetes was similar to the internal consistency of the measurement when used for persons with type 1 diabetes. There was a modest relationship between the subscales

DQOL and SF-36 (significant Pearson correlations ranged from 0.26 to 0.60). However, the SF-36 was less sensitive than the DQOL to lifestyle issues (i.e. the effects of diet, oral hypoglycemic agents, or insulin treatment.). The SF-36 did appear to be more sensitive to changes in the number and severity of complications. The authors concluded that while the two scales overlap they are not redundant, rather they compliment each other.

Ibrahim (Ibrahim et al., 2002) looked at the correlations between clinical indicators and health status measurement from 252 patients with type 2 diabetes. Measurements using the SF-36 instrument were taken at baseline and at 1 year after enrollment in a diabetes management program. HbA1c measurements significantly improved ($p < 0.001$) from 8.37 % (SD 1.79) to 7.19 (SD 1.1) over the 1 year period. At baseline, Hba1c showed statistically significant small inverse correlations (ranging from -0.197 to -0.12) with Physical Functioning, Role-Physical, Body Pain, General Health, and Role-Emotional. At one years time HbA1c had significant inverse correlations with Body Pain, general Health and Role physical, ranging from -0.182 to -0.210. There were no significant correlations between changes in HbA1c levels and changes in the SF-36 scores over the one year period. The authors commented that the correlations are relatively small, indicating the possible existence of other factors that may impact on self-perceived health status.

In a double-blinded randomized trial, Testa and coworkers (Testa et al., 1998) looked at the relationship between change in HbA1c and HRQOL outcomes. HRQOL was assessed using a battery of symptom measurements and visual analog scales of perceived health that were of unknown validity and reliability. The study compared glipizide gastrointestinal therapeutic system verses placebo over a 15 week period. Change in

HRQOL measures compares to change in HbA1c showed that increase in HbA1c levels of 1.0% or greater are associated with substantial decrements in HRQOL. Decreases of the same magnitude showed smaller, but clinically important, improvements in HRQOL.

2.4 Diabetes self-care activities in type 2 diabetes.

2.4.1 Diet

Medical nutrition therapy is an integral component of diabetes management and of diabetes self-management education (ADA, 2002). Medical nutrition therapy for people with diabetes should be individualized, with consideration given to the individual's usual food and eating habits, metabolic profile, treatment goals, and desired outcome.

The ideal dietary management plan for those with type 1 diabetes integrates insulin therapy into usual eating habits (Funnell et al., 1998). Individuals using conventional insulin therapy need to eat similar amounts with types of food at consistent times that are synchronized with the time actions of the insulin they take. They also need to monitor blood glucose levels and adjust insulin doses for the amount of food usually eaten based on blood glucose patterns.

The primary goal of nutrition therapy for persons with type 2 diabetes is to achieve and maintain normal blood glucose, lipid levels (Funnell et al., 1998) and reduce blood pressure (Franz et al., 2002). For prevention of type 2 diabetes, excess body fat is perhaps the most notable modifiable risk factor (Franz et al., 2002). Because most type 2 patients with diabetes are overweight and resistant to insulin, nutritional therapy should emphasize lifestyle strategies that result in reduced energy intake, usually through reducing the fat content of the diet, and increased energy expenditure through exercises. Even mild to moderate weight loss (5 to 10 kg) improves short-term glycemic control (Noble, 2001).

2.4.2 Exercise

It is now clear that regular physical exercise is important in both the prevention and treatment of type 2 diabetes (Hamdy, 2001). The benefits of exercise are many and include increased energy expenditure, which, combined with dietary restriction, leads to decreased body fat, increased insulin sensitivity, improved long-term glycemic control, improved lipid profiles, lower blood pressure, and increased cardiovascular fitness. As with individualized nutrition management, physical activity management needs to be tailored to each person's unique set of circumstances. Because of its effect on self-esteem and stress reduction, the addition of a regular exercise program can serve as the first step in self-directed behavioural change for many patients (Wheeler, 1999).

Whereas moderate-intensity exercise in nondiabetic persons has little effect on blood glucose concentrations, it is usually associated with a decrease in blood glucose toward normal in patients with type 2 diabetes. This effect may be used by patients to help regulate blood glucose concentrations on a day-to-day basis and may be a mechanism by which regular physical exercise results in improved long-term diabetic control (Hamdy, 2001; Wheeler, 1999). Exercise exerts a short-term effect on muscle glycogen, and it may not improve glycemic control as evidenced by HbA1c, in type 1 diabetes (Wheeler, 1999; Funnell, 1998).

The challenge for patients with type 2 diabetes is to get started on an exercise or physical activity program and to make it a part of lifelong behavior (Wheeler, 1999). For patients with type 1 diabetes, the challenge is learning to adjust the therapeutic regimen (insulin and nutrition management) to allow safe participation and high performance in all forms of physical activity consistent with desires and goals, and to avoid hypoglycemia which can occur during, immediately after, or many hours after exercise. Self management skills (collecting and interpreting self monitored blood glucose data and food data) and the increasing use of intensive insulin therapy provides patients with flexibility to make appropriate insulin dose adjustments for various activities

2.4.3 Medication for type 2 diabetes

Type 2 diabetes mellitus is a heterogeneous disorder; three basic metabolic defects characterize the disease: insulin resistance, an insulin secretory defect that is not autoimmune mediated, and an increase in glucose production by the liver (Ramlo-Halsted et al., 1999). Deterioration of control of the disease over time is common and is associated with progressive deterioration of beta-cell function that occurs independently of the initial therapeutic approach chosen (CPG-CDA 1998). Therefore, it can be expected that therapy for people with diabetes will have to be progressively augmented over time.

Universal agreement is lacking on the level of glycemic control at which pharmacologic therapy needs to be initiated (Riddle, 1999). Metabolic therapy for type 2 diabetes is taken in a stepwise approach (CPG-CDA, 1998), with advancement to the next level of therapy occurring when the individually determined target levels for control have not been attained in 2 to 4 months. Oral agent therapy is indicated in any patient with type 2 diabetes in whom diet and exercise fail to achieve acceptable glycemic control (DeFronzo, 1999), or initial therapy with diet and exercise for those that are obese. Diet and exercise continue to be important at all levels of glycemic control.

Current therapeutic agents available for type 2 diabetes include sulfonylureas, meglitinides, biguanides, thiazolidinediones, alpha-glucosidase inhibitors, and insulin (Reasner and Defronzo, 2001). Because the dominant defect in the early stages of type 2 diabetes is insulin resistance, it is recommend initiating therapy with an insulin sensitizer (Reasner and Defronzo 2001), with metformin being the drug of choice for those that are obese (BMI ≥30) (Nathan, 2002; Greenway, 1999). Post prandial blood glucose can be targeted with the use of an alpha-glucosidase inhibitor or a meglitinide. Insulin therapy is initiated if a combination of two oral agents fails to provide adequate glycemic control (Florence et al., 1999; Riddle, 1999). Ultimately, because of the progressive nature of the disease and the progressive decline in pancreatic beta-cell function, insulin therapy is almost always obligatory to achieve optimal glycemic goals (Mudaliar et al., 2001).

2.5 Methods in monitoring of glycemic control

Monitoring of glycemic status, as preformed by patients and health care providers, is considered a cornerstone of diabetes care (ADA, 2002; Funnell et al., 1998). The ability of people with diabetes to monitor daily changes in blood glucose has markedly improved the ability of control glucose levels (Meltzer et al., 1998). Results of monitoring are used to assess the efficacy of therapy and to guide adjustments in nutritional therapy, exercise, and medications in order to achieve the best possible BG control (ADA 2002).

2.5.1 Monitoring of glucose in urine

Both physicians and diabetic patients have traditionally relied on measurement of glycosuria as an indirect method of estimating plasma glucose concentration to guide adjustment of therapy (Hayford et al., 1983). Urine glucose monitoring was not used as a tool to achieve specific glycemic control, but was a guide for the health care professional to change therapy to relieve symptoms of hyperglycemia (Goldstein et al., 1997). However, despite the relatively low cost and ease of specimen collection there have been well-described limitations of urine glucose testing (Sacks et al., 2002; ADA, 2002; Goldstein et al., 1997; Hayford et al., 1983; Carney et al., 1983;Ohlsen et al., 1980; Epstein et al., 1980; Aleyassine at al., 1980)

The rationale for urine glucose testing is that urinary glucose reflects blood glucose levels during the period of urine production (Goldstein et al., 1997). Although glucose is detectable in the urine in patients with grossly increased blood glucose concentrations it provides no information about blood glucose concentrations below the variable renal glucose threshold (~10mmol/L) (Sacks et al., 2002), therefore, a patient would not be able to test for hypoglycemia via this method. A voided specimen collected 30 to 60 minutes since the previous void approximates the blood glucose level during the time of the specimen collection.

2.5.2 Monitoring of glycated hemoglobin.

Glycated hemoglobin (GHb) is formed under the process of glycosylation which occurs as glucose in the plasma irreversibly attaches itself to the hemoglobin component of the red blood cell (Funnell et al., 1994). GHb occurs in several variants and can be measured using several different techniques, with HbA1c being the most frequently measured in practice (Coster et al., 2000). The process of glycosylation increases in proportion to the blood glucose level over the preceding 3-4 months (Funnell et al., 1994; Sacks et al., 2002). It is not a simple mean of the glucose concentration over the last 3-4 months, but a weighted mean (Funnell et al., 1994). In effect, 50% of the HbA1c level is determined by the preceding month, 25% of the level is determined by the one month level before that. Finally, the remaining 25% of the HbA1c is determined by the plasma glucose levels during the two-month period before the past two months.

There is now good evidence to support the use of HbA1c measurements in the assessment of glycemic control (Coster et al., 2000) with conclusive evidence concerning the relationship of the measurement with the risk of microvascular complications in both type 1 (DCCT, 1993) and type 2 diabetes (UKPDS, 1998). Recommended targets of glycemic control for adults and adolescents with diabetes mellitus from the CDA (Meltzer et al., 1998) is presented in Table 2.2. For those with type 1 diabetes, the DCCT demonstrated that an 1.9% absolute reduction in HbA1c translated to a 76% reduction in retinopathy, 34% reduction in nephropathy, and a 69% reduction in neuropathy (DCCT, 1993). The UKPDS demonstrated that a reduction of 1% HbA1c was associated with reductions in risk of 21% for any endpoint related to diabetes, 21% for death related to diabetes, 14% for myocardial infarction, and 37% for microvascular complications (Stratton et al., 2000).

Table 2.2: Levels of glucose control for adults and adolescents with diabetes mellitus.

	Level of Control			
	Ideal (normal nondiabetic)	Optimal* (target goal)	Suboptimal$^{\perp}$ (action may be required)	Inadequate^{+} (action required)
HbA1c assay	0.04-0.06	<0.07	0.07-0.084	>0.084
Fasting or premeal glucose level (mmol/L)	3.8-6.1	4-7	7.1-10	>10
Glucose level 1-2h after meal (mmol/L)	4.4-7	5.0-11	11.1-14	>14

*These levels are likely related to minimal long-term complications but may be impossible to achieve in most patients with type 1 diabetes with current therapies

$^{\perp}$ Attainable in the majority of people with diabetes but may not be adequate to prevent complications

$^{+}$ These levels are related to markedly increased risk of long-term complications, requiring a reassessment and readjustment of therapy.

Adapted from: Meltzer et al., 1998.

Both the ADA and CDA recommend measurement of hemoglobin A1c for the monitoring of glycemic control in patients with known diabetes, but not for diagnosis of diabetes (Sacks et al., 2002; Meltzer et al., 1998). The CDA recommends the testing for glycated hemoglobin should be preformed on a periodic basis to assess overall glucose control (Meltzer et al., 1998); HbA1c should be measured every 3 to 4 months in all patients taking insulin and at least every 6 months in people on nutrition therapy or oral hypoglycemic therapy.

2.5.3 Fructosamie

Serum proteins (mostly albumin) also undergo a process of glycation (Coster et al., 2000). The turnover rate of human serum albumin is much shorter (half-life 25 days) than that of hemoglobin (half-life 120 days)(Coster et al., 2002), thus a glycated serum protein test (fructosamine), measures glycemic control over 2 to 3 weeks (Funnell et al., 1998). Measurements of total glycated serum protein and glycated serum albumin correlate well with one another, with the fructosamine assay being the most widely used technique of measurement (Coster et al., 2000). Normal ranges vary among different methods of measurements.

Fructosamine values are used in short-term follow-up of interventions that have been recently implemented to lower blood glucose (Funnell et al., 1998; Bouche et al., 2002; Winocour et al., 1989). Since, it is sensitive to short-term fluctuations more so than HbA1c, it has been argued that it is not useful in clinical practice (Coster et al., 2000).

2.6 Self-Monitoring of Blood Glucose

The CDA recommends that SMBG is an essential component of the therapeutic plan of all people with type 1 diabetes, insulin treated people with type 2 diabetes, and pregnant women with preexisting diabetes or gestational diabetes. Self-monitoring of blood glucose is an integral component of the therapeutic plan for the majority of people with type 2 diabetes treated with oral hypoglycemic agents. It may be useful for people with type 2 diabetes controlled by diet alone. No recommendations are made, however, on the frequency of SMBG.

In comparison, the American Diabetes Association's (ADA) recommendation (ADA, 2002) on SMBG frequency is 3 times daily for those with type 1 diabetes and is recommend for all patients using insulin. The ADA guidelines state that for those patients with type 2 diabetes, the optimal frequency and timing of SMBG is not known. Nor is the role of SMBG in stable, diet-treated patients with type 2 diabetes known. The ADA's expert consensus is to include SMBG in the diabetes management plan, with routine evaluations of the patient's technique and ability to use data to adjust therapy.

The National Institute for Clinical Excellence (NICE) guidelines for the management of blood glucose in type 2 diabetes state that insulin doses can only be adjusted appropriately on the basis of SMBG levels at different times of the day (NICE, 2001). The guidelines recommend that self-monitoring should not be considered as a stand-alone intervention. Self-monitoring should only be taught if the need/purpose is clear and agreed with the patient. SMBG may prove useful to people in their overall approach to self-care, particularly for individuals that are moving in the direction of stepping up therapies. No recommendations on frequency of SMBG are stated in the guidelines, and professionals are asked to reconsider the almost automatic assumption that SMBG is beneficial.

2.6.1 Self-monitoring of Blood Glucose in Type 1 DM

SMBG is considered an essential component of management of type 1 DM in the current clinical practice guidelines from the Canadian Diabetes Association (CDA-CPG) (Meltzer et al., 1998). Clear evidence for self-monitoring of blood glucose (SMBG) within a complete package of DM management is demonstrated in the Diabetes Control and Complication Trial (DCCT) (Coster et al., 2000).

In the DCCT, home glucose monitoring in the group receiving standard therapy was carried out primarily by urine glucose testing combined with SMBG to achieve and maintain clinical well being. (DCCT, 1987). The standard therapy group did not receive targets for glycemic control, but the subjects' therapy was adjusted if their hemoglobin A1c (HbA1c) was 2 standard deviations above the mean (13.1%) for patients with type 1 DM. The results showed that the intensively treated group had demonstrated a delay of onset and a slowing of the progression of diabetic retinopathy, nephropathy, and neuropathy in type 1 diabetes (DCCT, 1993). However, since the differences in self-monitoring between groups were confounded with differences in every aspects of DM care, the independent contribution of SMBG to the outcome of the study cannot be estimated (Coster et al., 2000).

Despite the evidence from the DCCT supporting tight glycemic control for those with type 1 DM, studies have not shown conclusive support for SMBG in persons with type 1 DM. Low statistical power, poor reports, insufficient testing, inaccurate testing have been explanations for these outcomes (Coster et al., 2000; Strowing et al., 1998).

Newman et al., (1990) concluded that SMBG alone did not improve HbA1c levels compared to those who did not monitor their BG levels. 21 subjects using SMBG and 17 subjects not performing SMBG in a veteran population were matched based on age, duration of illness, ancillary illness, hospitalizations and DM complication. No statistical differences in HbA1c were seen between the two groups for the 3-year study period.

Likewise, Belmonte et al., (1998) observed no statistically significant change in HbA1c values. The study involved 219 juvenile (ages 1 to 21 years) subjects over a three-year period. Subjects were instructed to perform SMBG at least before breakfast, before supper and, in addition, at bedtime when their urine test was negative for glucose. Every two weeks the patients (or guardians) were to report blood glucose test results that were outside 5.6mmol/L to 8.3mmol/L. Based on these 2-week reports, the clinic staff would adjust the subjects' insulin. No significant differences in HbA1c were seen over the three-year period (HbA1 11.4% year 1 and HbA1 11.8% at year 3). There were also no significant differences in the level of HbA1 between age and sex groups, monitoring score, number of daily injections, nor level of serum cholesterol.

The authors attributed the lack of significant findings to the failure of the subjects to adhere to frequent SMBG. Also, failure of subjects to report hyperglycemia to the clinic, which would have allowed for the adjustment of insulin, was another reason reported by the authors for the absence of significant findings. Additional reasons for lack of an effect of SMBG on HbA1 were also hypothesized. These hypotheses included insufficient recommendations in SMBG, blood glucose targets were insufficiently stringent, and more intensive frequency of insulin administration should have been implemented.

Daneman et al., (1985), concluded that the addition of SMBG to routine care does not lead to improved metabolic control in type 1 DM. This was based on a double crossover study involving 16 children (mean age 13.1 years old) who were assigned to one of two groups. Group A monitored urine and SMBG from weeks 1 through 13. From weeks 14 through 26 group A monitored urine only. Group B monitored urine only from weeks 1 to 13; in addition to urine glucose monitoring, SMBG was added from weeks 14 through

26. Insulin dosages were adjusted once or twice weekly depending on patterns of blood and/or urine glucose readings during the previous 3-7 days. Both groups showed a trend toward decreasing mean BG; however, these trends did not reach statistical significance. There were also no significant changes in HbA1c at any time.

A non-randomized study done by Geffner et al., (1983) suggests that multiple injections of insulin combined with SMBG improved glycemic control. Subjects included in the study consisted of sixty-three consecutive patients (ages 1 to 21 years old) that attended a pediatric diabetes clinic. Of the 63 patients, 53 patients chose SMBG combined with an insulin regimen of 2 or more injections per day. Mean stable glycosolated hemoglobin fell from 12.9% to 11.0% ($p<0.05$) six months after the intervention. Poor compliance (n=6) or parents wanting their children to continue with urine glucose testing (n=4) was the cited reasons for 10 patients not pursuing the SMBG.

An observational study done by Evans et al., (1999) used a population based register of patients with type 1 and type 2 DM. The total number of blood glucose strips dispensed in the previous 6 months and HbA1c were used in the regression analysis. The study also provided insight into SBMG practices in the community. The analysis of data for people with type 1 DM suggested for every extra 180 test strips dispensed, which would be equivalent to one extra test per day over 6 months, there was a 0.7% ($p<0.001$) decrease in HbA1c. It was also observed that 16% of the subjects obtained no strips at all, and only 1% of the subjects obtained enough strips to test at least four times daily. For those with type 2 DM, there was no association between the number of strips dispensed and HbA1c. This included insulin users with type 2 DM.

Terent and co-workers (1985) used a factorial study design, which randomized subjects to receive education or not for 6 months (phase I). In phase II subjects were randomized to receive SMBG or not followed by a 6 month follow up. Thus, the subjects were divided into 4 groups in this 18-month study. Group A (n=10) consisted of subjects educated in phase I and practice SMBG in phase II. Group B (n=8) subjects were not educated in phase I, but started SMBG in phase II. In group C (n=9) subjects were educated during phase I, and then left to follow-up. Lastly, group D (n-10) continued their pre-trial treatment.

Subjects in groups A and B were instructed on the use of SMBG visual strips. The subjects were requested to perform a test daily, with 4 tests being done twice weekly. The 4 tests done twice weekly consisted of a test before breakfast, 1 to 2 hours post prandial for the subjects main meals, and at bedtime. They were also instructed to adjust their insulin doses to target pre-meal blood glucose values below 7mmol/L and post-prandial values below 10mmol/L.

There was a significant decrease ($p<0.005$) in HbA1c for patients in groups A and B who practiced SMBG. This decrease was seen during the SMBG period for both groups. A non-significant decrease was seen in group B from 11.2 to 10.2%. Group D demonstrated a significant decrease (Table 2.3) in HbA1c from the beginning of the study to month 12. This decrease in HbA1c from months 0 to 12 in group D was attributed to the use of SMBG by one woman who became pregnant and lowered her HbA1c value from 12.2% to 3.8%. After her pregnancy, her HbA1c increased again. Overall, group D did not show a significant decrease in HbA1c.

Table 2.3. HbA1c Values (%) Reported in Terent et al., (1985).

	Months			
Group	**0**	**6**	**12**	**18**
A	12.3 +/- 3.2	12.2 +/- 3.2	11.0 +/- 2.6	10.2 +/- 1.9
B	11.8 +/- 1.4	12.3 +/- 2.5	10.8 +/- 1.0	9.8 +/- 3.0
C	11.2 +/- 2.0	10.1 +/- 1.7	9.9 +/- 2.5	10.2 +/- 2.1
D	11.1 +/- 2.3	10.0 +/- 2.0	9.5 +/- 3.2	10.4 +/- 2.1

2.6.2 SMBG in Type 2 DM

The importance of strict glycemic control in the type 2 population has been demonstrated in a recent clinical trial. In the United Kingdom Prospective Diabetes Study it is suggested that not only those individuals with type 2 DM and high blood sugars benefit from tight glycemic controls, but this also applies to those in any diabetic blood sugar range (Stratton et al., 2000).

Five randomized control studies with type 2 subjects have been published comparing SMBG to not monitoring (Wing et al., 1996; Muchmore et al., 1994; Estey et al., 1990; Rutten et al., 1990; Fontbonne et al., 1989). Three studies that involved an educational component with SMBG added to the experimental groups (Estey et al., 1990; Wing et al., 1996; Muchmore et al., 1994) did not separate out the effect of SMBG testing from the effect of the education intervention. Small sample sizes and provision of free testing supplies are additional methodological problems that limit the assessment if the effect if SMBG alone in these studies.

In the paper by Estey et al., (1990), the study was designed to address the hypothesis that there would be no differences in HBA1c, SMBG frequency, and weight change between those who received a follow-up program and those who did not receive the intense follow-up. Both the experimental and the control groups received the standard 3 day education program, that included instruction on SMBG, meal planning and exercise instructions. The experimental group, in addition to the 3-day program, also received both a home visit and telephone interventions to reinforce diabetes management behaviors.

While there were no significant differences in the HbA1c values between the two groups (Table 2.4), there was an improvement in values within the groups. The authors indicated that SMBG practices, as a measure of compliance, was found to be higher in the intervention group, although it is unclear if this difference was formally tested.

Table 2.4. HbA1c Values (%) reported in Estey et al. (1990).

HbA1c	**Control (n=25)**	**Intervention (n=28)**
Pretest mean	6.1 +/- 1.4	6.3 +/- 1.1
Posttest mean	5.8 +/- 1.5	5.6 +/- 0.7
Mean Change	0.3 +/- 0.7	0.7 +/- 0.9

The study by Wing et al. (1990) involved a behavioral weight control program, with the experimental group being taught to monitor blood glucose. The aim of the study was to determine if SMBG added to the behavior program would improve dietary compliances. The focus of the control group was weight reduction, while the SMBG group was to observe the relationship between blood glucose, eating, and exercise. Financial contracts were made with each individual to refund monies based on outcomes measured for their specific treatment group designation.

Both the control and experimental group met at regularly scheduled meetings. Each meeting (weekly for 12 weeks, monthly for the next 6 months, and follow-up at 9 and 12 months) consisted of individual weigh-ins, discussion of behavior modification for weight control, and the subject's blood glucose levels were checked at each meeting. Subject's medications were adjusted from a standard algorithm based on the blood glucose levels from the meeting.

Testing supplies were provided at no charge to subjects in the monitoring group up to week 37. After this time subjects were encouraged to purchase supplies on their own. The initial results at week twelve showed significant differences between the control and intervention groups (Table 2.5). However, HbA1c values measured at week 62 returned to baseline levels in the monitoring group.

Table 2.5. HbA1c Values (%) Reported in Wing et al. (1990).

	Weight Control group (n=22)	**Glucose Monitoring group (n=21)**
Week 0	10.86 +/- 2.00	10.19 +/- 2.51
Week 12 (free supplies)	10.00 +/- 2.08	9.68 +/- 1.95 (p<0.001)
Week 62 (no free supplies)	10.44 +/-2.16	10.19 +/- 2.29

The study by Muchmore et al. (1994) was designed to test the hypothesis that dietary carbohydrate counting coupled with SMBG might benefit type 2 diabetic patients. The control and intervention group received education on a formal behavior weight loss program and one-on-one counseling by a diabetes educator and dietician. In addition, the intervention group received individual teaching on carbohydrate counseling and SMBG, and the control group received an equal proportion of attention focusing on diabetes nutrition.

The results showed no differences between the groups (n-23). However, itis interesting to note that there was a significant decrease from the pre to the post HbA1c tests for the intervention group (1.54% p<0.05). The authors indicated that the control group only showed an "incremental, insignificant improvement of 0.84%".

In this study, participants were provided with free testing supplies for a limited time. After week twenty of twenty-eight, it was left up to the individuals to carry out SMBG at their own "election and expense". However, unlike Wing (1996), continued improvement was seen in HbA1c values in the experimental group, with a significant difference in values (1.54% improvement) within the group from week 0 to week 44. The control group patients, who were not counseled on SMBG, had no significant changes in HbA1c in the same time period. There were no significant differences between the groups.

Improvements in HbA1c was also seen by Schwedes (2002) when comparing structured SMBG combined with dietary counseling versus a group that focused on diet lifestyle. The intervention group were instructed to perform SMBG six times (before and 1hr after main meals) on 2 days per week. SMBG results were to be recorded along with documentation of eating habits and their state of well-being. It was explained to the patients that SMBG plus their diary would provide them with information about their day-to-day glycemic control, allowing them to make appropriate adjustments to their diet and lifestyle, eventually resulting in improved diabetes control. These patients were seen every 4 weeks during the 24 weeks of intervention. Patients also received a defined counseling algorithm. The control group received non-standardized counseling focusing on diet and lifestyle.

After 6 months of intervention, significant differences in HbA1c (p = 0.0086) were seen between the intervention group (7.81% +/- 1.52%) and the control group (7.47% +/1 1.27%). During the additional 6 month follow-up, 87% of the patients in the intervention group continued SMBG with their metabolic status remaining stable. A subgroup analysis of the intervention group identified 24% of the patients as non-responsive. Theses patients performed the tests frequently and accurately, but did not manage to act on their findings (lacked self-regulation).

A randomized cluster study performed by Rutten (Rutten et al., 1990) did show a positive improvement of HbA1c via SMBG. Patients in the monitoring group reported their fasting blood glucose results monthly to a practice nurse, and the control group consulted their doctor at least four times in this study that was carried out over 1 year. This was part of a trial protocol with the overall aim of moderating frequency of physician consults based on metabolic (SMBG) regulation, with overall emphasis on weight reduction.

The control group patients were not instructed in SMBG. During the study period, subjects in the control group were counseled at each physician visit on their current blood glucose level, and on diabetes behavioral management. The doctor's visits were not at fixed intervals, but "frequency [was] partly dependent on regulation of the diabetes, and partly on choice." Patients whom were overweight were referred to dieticians.

Instructions on SMBG were given to the experimental group on 2 to 5 occasions. At their monthly reports to the practice nurse, if a value was <4.4 mmol/l or >10mmol/l they were referred to the doctor. Fix targets of weight and glucose regulation were combined with a medication protocol; with the provision to refer to an internist for patients that were not controlled (i.e.<10mmol/l) on diet and maximal dosages of oral hypoglycemic agents.

Rutten et al (1990) were successful in showing a significant decrease in HbA1c (9.7% to 9.2% p<0.05, n=55) in the experimental group. In fact, the control group's HbA1c increased significantly (8.9% to 9.4% p<0.001, n=72). Unfortunately, this study showed only the feasibility of the study protocol of regulation of doctor consults. It is not possible to separate the protocol from the results to analyze the effect that the intervention had on comparing the SMBG verses no-SMBG.

A randomized control trial reported by Fontbonne et al. (1989) did not have a formalized educational component involved. However, patients did have fixed scheduled appointments in which the consulting physician was allowed to modify dietary and medications based on results obtained from their study group status. The study, which lasted over six months, had three testing arms: a) HbA1c every 2 months (n=54) b) urine self-testing twice every other day (n=54) c) SMBG twice every other day (n=56).

All groups were on a regimen to follow-up with their physician. The information about BG control provided to the physician was limited to the results from the tests carried out in the patients' respective arm. But, without controlling for the fixed physician visits, it is difficult to determine if it was a monitoring intervention results we were observing or the results were due to a physician intervention.

It is interesting to note that there was a significant correlation (r=0.36 p<0.02) in the number of blood glucose strips used, and the decrease in HbA1c. The greater the number of strips used the greater the HbA1c decrease. For those monitoring with urine test strips, no correlation was found. This is an interesting finding since the study's monitoring protocol was regimented. When monitoring compliance was compared, it was found that SMBG group was significantly more compliant than the urine testing group.

A recent randomized control trial compared the outcomes of subjects in an intervention group that were to receive care from a pharmacy with Certified Diabetes Educators (CDE), versus the control group that received care from their usual pharmacy (Guirguis et al., 2001). Certification as a CDE recognized competencies in specialized area and requires performance in knowledge, skill and patient care (Kirk et al., 1998). Patients in both groups were provided with free testing supplies for the duration of this 6-month study. The results showed that glycemic control in the intervention group significantly improved ($p<0.01$, $n=24$). However, the control group that received their usual pharmacy care, also showed a significant improvement in their glycemic control ($p<0.01$, $n=23$). There were no significant differences between the usual care group and those under the care of a CDE pharmacist.

Guirguis et al hypothesized that the significant improvement of both groups and the lack of differences between the two groups may have been due the provision of free testing supplies. The rational for providing free testing supplies was to remove barriers to SMBG and to act as an incentive to participate in the study. However, the effect of providing free testing supplies cannot be attributed to the improvements in the groups, without a third study group receiving neither the intervention of a CDE pharmacist or the supply incentives.

A retrospective study done by Meier and colleagues (Meier et al., 2002) compared patients' baseline average testing frequency and HbA1c with those obtained during a 6-month interval beginning 2 months after implementation of a modified Veteran's Affair gluidelines on SMBG. The original guidelines recommend SMBG twice weekly for those patients with type 2 diabetes and on oral agents or diet therapy. At baseline average HbA1c was 7.83% (SD 1.34%) with a frequency of SMBG of 1,36 (SD 0.95) strips per patient per day. Post implementation mean HbA1c was 7.83% (SD 1.54%) p=0.63 versus baseline. Frequency of SMBG decreased by 46% to 0.74 (SD 0.5) strips per patient per day (p<0.0001). For those with diabetes and on diet therapy there was a significant mean decrease in HbA1c of 0.07% (p<0.0001) and likewise a 35% decrease (p<0.0001) in SMBG from 1.07 strips (SD 0.90) per patient per day to 0.70 strips (SD 0.51) per patient per day. Similar findings were observed for those in the drug-treated cohort of patients. Linear regression analysis showed no significant impact on individuals' HbA1c with reduction in strip use.

It was concluded by Karter and colleagues (Karter et al., 2001) that more frequent SMBG was associated with clinically and statistically better glycemic control regardless of diabetes type or therapy. In this study, a cohort design was used that included 24,312 adult patients with diabetes who were part of the managed care organization. The authors estimated the difference between HbA1c levels in patients who self-monitored at frequencies recommended by the American Diabetes Association compared with those who monitored less frequently or not at all. Self-monitoring among patients with type 1 diabetes (>/=3 times daily) and pharmacologically treated type 2 diabetes (at least daily) was associated with lower HbA1c levels (1.0 percentage points lower in type 1 diabetes and 0.6 points lower in type 2 diabetes) than was less frequent monitoring (P <0.0001). Although there are no specific recommendations for patients with nonpharmacologically treated type 2 diabetes, those who practiced self-monitoring (at any frequency) had a 0.4 point lower HbA1c level than those not practicing at all (P <0.0001).

Cross-sectional studies have also looked into frequency of SMBG and metabolic control (Franciosi et al., 2001; Good et al., 2001; Wieland et al., 1997). Franciosi and colleagues explored the relationships between SMBG, metabolic control and quality of life (QoL). From a total of 3,567 patients with type 2 diabetes, approximately 2,255 non-insulin using patients with diabetes were involved in the study. Clinical variables were gathered by obtaining the last value recorded in the previous 12 months. Patients were requested to complete a questionnaire investigating SMBG practice, presence and severity of diabetes. QoL was investigated by using a diabetes specific measure; the Patient Outcomes Research Team diabetes 2 (PORT). To evaluate the presence of depressive syndromes the Centers for Epidemiologic Studies-Depression (CES-D) scale was used.

Approximately 45% of the patients who were not on insulin reported that they never performed blood glucose self-testing. Only 10.8% of the subjects preformed SMBG greater than once daily. 30% of subjects preformed SMBG greater than once weekly and 14.6% of subjects preformed SMBG less than once weekly. Poorer metabolic control was related to a frequency of SMBG ≥1 per day or ≥ 1 per week. The authors concluded that patients with a higher frequency of SMBG was related to higher HbA1c levels, suggesting that patients with poor metabolic control have a greater tendency to self-monitor.

In an abstract published by Good and colleagues (Good et al., 2001) it was reported that there were differences in mean HbA1c values for those who had received SMBG strips in Veteran Affairs facilities verses those who did not receive test strip in the facilities. 2,912 patients who had received strips had a mean HbA1c of 7.92%. In comparison, the mean HbA1c was 7.34% for those patients (n=2,221) who did not receive test strips in the facilities. Differences persisted after controlling for potential confounders. The authors concluded that the presence of more DM complications in the group that had obtained strips suggest that strips may be used more often in difficult to control subjects.

A retrospective study done by Wieland and colleagues (1997) looked at the relationship between HbA1c and frequency of SMBG using outpatient pharmacy records from 216 Veteran's Affairs recipients. Patients were included in the study if they were male, had their HbA1c measured between September 1, 1994 and September 30, 1995, and had an active prescription for glyburide at a constant dosage for at least three months before the most recent HbA1c. They also compared three groups of patients; those that were performing SMBG a) two or more times daily, b) once daily, c) and not performing SMBG. After controlling for clinical and demographic variables, the authors reported that there was no significant relationship between frequency of SMBG and HbA1c ($r = 0.02$, $p>0.50$). There were no significant differences between HbA1c between the three groups.

Evans (1999) studied the patterns of SMBG in both type 1 and type 2 persons with diabetes and who were on insulin. 16% of people with type 1 diabetes obtained no strips at all, and among 807 patients with type 1 diabetes, 128 (16%) did not redeem any prescriptions for glucose monitoring reagent strips in the 3 year study period. Only 161 (20%) redeemed prescriptions for enough reagent strips to test glucose daily. The corresponding figures for the 790 patients with type 2 diabetes who used insulin were 162 (21%; no strips) and 131 (17%; daily tests). Reagent strip uptake was influenced both by age and by deprivation category. The authors concluded that SMBG concentration is associated with improved glycemic control in patients with type 1 diabetes. They also concluded that regular SMBG monitoring in patients with type 1 and type 2 diabetes is uncommon.

Blonde (Blonde et al., 2002) looked at frequency of blood glucose monitoring in 228 patients with type 2 diabetes in four outpatient health clinics. Patients were classified as "regular SMBG performs" if through the 3-year period, almost all visits with physicians in 4 clinics documented frequency of SMBG and results. A patient was labeled "irregular SMBG performer" if there were few mentions of SMBG documented and/or if documentation did not contain the frequency of SMBG. Finally, patients were labeled "not monitored" if there was no mention of SMBG or if documentation noted that the patient was not monitoring.

Approximately 21% of patients were classified as regular SMBG preformsers. 71% of these performers had HbA1c levels $\leq$ 8%. For the 42% of patients who were irregular SMBG performers and the 37% of patients not monitoring, only 18% and 22%, respectively, had HbA1c $\leq$ 8% ($p<0.0001$). The authors concluded that regular monitoring and consistently discussing blood glucose appeared to be positively associated with a better glycemic control.

The interrelationship of blood glucose levels at different times of the day and HbA1c was explored in patients with non-insulin treated type 2 diabetics subjects in a study done by Bonora (Bonora et al., 2001). Subjects (n=856) had plasma/blood glucose assessments before and 2-3 hours after breakfast, lunch. HbA1c was also measured. Correlations between HbA1c and plasma/blood glucose levels ranged from 0.44 to 0.67 (P <0.01). Multiple regression analyses showed that premeal, but not postmeal, plasma/blood glucose levels were independent predictors of HbA1c.

The authors concluded that glucose monitoring in type 2 diabetes seems to be more complex that previously thought, because fasting plasma glucose is rather a poor index of glucose levels throughout the day. They also sugest that there is good evidence that several glucose determinations over a period of several weeks are better correlated to HbA1c than a single or a few glucose determinations on a single day.

2.7 Barriers to SMBG

It is evident that low levels of adherence to SMBG continue to occur despite its perceived importance in the self-management of diabetes (Jones et al., 1996). In order to make decisions about diabetes therapy adjustments, sufficient and consistent BG data is required (Funnell et al., 1998; Jones et al., 1996; Meltzer et al., 1998; ADA, 2002; Blonde et al., 2002). Individuals often have the prerequisite knowledge and skills yet have reasons for testing or not testing blood glucose at a particular time. Awareness of these reasons and barriers to self-care activities would be helpful in understanding these complex behavioral responses.

New research has engendered the development of new measures of health and illness (Anderson RM et al., 1997), and researchers have recognized the need for measurements that assess self-care activities and barriers to care for diabetes research (Toobert et al., 2000; Irvine et al., 1990). These self-care activities and perceived barriers have been studied separately (Toobert et al., 2000; Karter et al., 2000; Ruggiero et al., 1997; Irvine et al., 1990), however, the relationship between these activities has not yet been studied.

Little behavioural analysis has been done concerning barriers to testing blood glucose (Jones et al., 1996; Aljasem et al., 2001). The measurement of perceived environmental barriers to self-care is grounded in social learning theory (Irvine et al., 1990). It proceeds from the assumption that a given barrier to self-care, such as a person's work schedule, has a differential psychological effect among individuals, and thus affects their self-care behaviour differently. Understanding the influences of barriers on behaviour is a prerequisite for changing behaviour and designing specific, individualized interventions (Jones et al., 1996). Potential barriers to SMBG include the cost of testing strips, language barriers, inadequate educations about its benefits, patient discomfort, and patient inconvenience (Karter et al., 2000; Nyomba et al., 2002;

Aljasem and colleagues (Aljasem et al., 2001) measured blood glucose testing by asking 309 people with type 2 diabetes "How many times per day, on the average, did you test your blood for sugar level?" Five self-efficacy items were included that measured a subjects judgment in their ability to monitor, plan, and carry out diabetes activities in daily life. Results of a step-wise multivariate analysis showed that education was the only sociodemographic variable that significantly related to frequency of blood glucose testing (β=0.16, P=0.01). It appeared that education facilitates understanding of testing procedures and using the results to improve glycemic control. Also, the authors speculated that since higher-educated persons generally have higher income, they are better able to afford blood testing equipment and supplies.

When self-efficacy variables were entered into the model, the effect of education was reduced and became non-significant (β = 0.09, P = 0.20). This reduction may be due to the indirect effect of education on blood glucose testing by affecting self-efficacy. The authors hypothesized that subjects with high self-efficacy may have felt comfortable with less frequent testing in spite of others' interest in having them test more often.

Cost as a barrier to SMBG was examined in a single-blinded, control matched, longitudinal study of patient with insulin-requiring diabetes in a study carried out by Nyomba and colleagues (Nyomba et al., 2002). Sixty-two patients who were treated with at least 2 insulin injections per day for at least 1 year, had a HbA1c >120% of upper limit of normal, and had recent diabetes education participated in this 12 month study. Patients completed questionnaires reporting SMBG frequency, perceived barriers to SMBG, monthly income, and any private health insurance plans that cover for SMBG testing. Patients were then randomly assigned to two groups, matched on age, sex, education, income, insurance coverage, type of diabetes, duration of diabetes, number of years on insulin, frequency of SMBG, random blood glucose, HbA1c, and number of daily injections. 50 strips were provided to the control group who were instructed to purchase additional strips as needed. The intervention group was given 100 strips per month at no extra cost. Subjects were not given any information on frequency of testing in either group.

Drops out rates in the intervention group and control group were 19% and 48% respectively. The main reported barrier at the to SMBG was inconvenience (47% and 29%) at the start and end of the study respectively. Cost of SMBG strips was the second highest reported barrier to SMBG at the start of the study (31%) but was the fourth reported barrier at the end of the study (10%). Results showed that SMBG frequency increased with time and was higher in the intervention group than in the control group (2.0 (SD 0.2) vs. 1.4 (SD 0.1) p<0.05) during the first 4 months. Insulin dose increased ~1.5-fold in the control group (p<0.05) but not in the intervention group. HbA1c initially decreased in both groups and then increased in the control group, and final HbA1c was lower in the intervention group than in the control group (8.7% (SD 0.3) vs. 9.9% (SD 1.1), P<0.01).

Likewise, Karter et al. (Karter et al., 2000) explored financial barriers to SMBG. 44,181 members (47.0%) of the Kaiser Permanente Northern California diabetes registry who controlled their diabetes by medication participated in a health survey that included questions on SMBG. Karter observed that SMBG practice patterns may be sensitive to out-of-pocket expenditures for SMBG strips. The largest decrease in the frequency of SMBG practice with increasing out of pocket strip cost was observed in subjects from neighborhoods with the lowest average annual income.

Chapter 3

Methods

3.1 Study Design

This was a cross-sectional study that utilized the baseline data from the first 200 patients that completed a survey and blood work for enrollment into a prospective, randomized, control trial. The baseline data collected was analyzed to assess cross-sectional relationships between SMBG behaviors, health, and glycemic control. The 200 subjects were recruited through a network of community pharmacies in Alberta (i.e., Edmonton and Calgary) and Saskatchewan (i.e., Regina) over an 8 month period starting in November 2001.

3.2.0 Subjects

3.2.1 Inclusion/Exclusion criteria

Those subjects eligible for inclusion had the following characteristics:

1) had type 2 diabetes,
2) not on insulin,
3) had been diagnosed with diabetes more than 1 year pre-enrollment,
4) were of 30 years of age or older, and
5) able to give consent for participation.

Those that controlled their diabetes by diet alone were included in the study if they meet the stated criteria. Subjects that had type 2 diabetes that were control by oral agents or diet alone were recruited because the aim of the study is to clarify and add to literature in this group of patients.

Subjects who were pregnant were excluded from the study due to metabolic changes that relate to the trimester of pregnancy. Also, those on insulin were excluded from the study since the use of SMBG for those on insulin is considered essential by the CDA (Meltzer et al., 1998).

3.2.2 Recruitment and Enrollment Procedures

As there was not a central mechanism that allowed for random selection from the population, the study relied upon the recruitment of volunteers. The initial 200 subjects were recruited in Edmonton, Calgary, and Regina through a network of community pharmacies. Study pharmacists were trained at investigators meetings to explain the study's purpose, procedures and ethical considerations and answers questions.

Study pharmacists carried out the recruitment and enrollment of subjects into the study. A variety of methods were used to facilitate recruitment; including posters in the community, bag stuffers at the pharmacy, advertisements in local newspapers, and community television stations. Interested individuals were asked to contact their local participating pharmacy. Individuals were also approached by their community pharmacist for participation in the study. Pharmacists identified patients through a) drug utilization reports b) patient requests for refills of their oral hypoglycemic agents c) "Diabetes Days" information clinics that were held by the community pharmacy.

Study pharmacists explained the study procedures and provided a study information letter (Appendix 1) that outlined the purpose, procedure, risks/benefits, confidentiality, and contact information. Interested subjects then completed the study consent form

(Appendix 1). After consent was obtained, the study pharmacists completed the case report forms (CRFs) (Appendix 2) with the subject. Subjects were then asked to fill out a 20-minute survey. Subjects were asked to complete the questionnaire at their own convenience and mail back to the research office in an envelope provided. Participants were provided with a laboratory requisition form and instructed to go to their nearest laboratory in order to provide a blood sample for the HbA1c analysis.

3.3.0 Measurements

Initial assessment at baseline included the completion of a short battery of health status and behavior questionnaires (Appendix 2). Four previously developed and validated instruments were used, namely the Summary of Diabetes Self-Care Activities (SDSCA), the RAND-12 Health Status Inventory, Environment Barriers to Adherence Scale (EBAS), and the Hypoglycemia Fear Survey (HFS). Demographic and self-reported clinical information regarding duration of diabetes, medical conditions due to diabetes, diabetes education experience were also requested.

3.3.1 Summary of Diabetes Self-care activities (SDSCA)

The SDSCA is a previously developed and validated measure of self-efficacy with diabetes self-care behaviours (Toobert et al, 2000). The 11 questions in the SDSCA assess 6 dimensions of the diabetes self-care regimen: general diet, specific diet, exercise, blood glucose testing, foot care, and smoking. Level of self-care for each dimension is assessed in this questionnaire, and not adherence or compliance to a prescribed regimen. This is because of the difficulties associated with identifying, for a given patient, a specific unchanging standard against which behaviors should be compared (Toobert & Glascow, 1994). Participants rate the number of days per week that they performed each self-care activity. The questionnaire is brief and provides for ease of scoring. With the exception of the specific diet dimension, the instrument has shown adequate internal consistency (Toobert et al., 2000). Raw scores for each measure are to be converted to standard scores with a mean of zero and a standard deviation of one in order to weigh all items equally.

Performance to recommended frequency of SMBG will be assessed by using the two SMBG questions in the SDSCA. The average of these two items represents the $\text{SDSCA}_{\text{SMBG}}$ score.

3.3.2 Fear of Hypoglycemia

The Hypoglycemia Fear Survey (HFS) (Cox et al., 1987) was used to assess levels of worry of impact of low blood glucose. The HFS has been developed and tested in patients with both type 1 and type 2 diabetes. In its current form it is a 23-item questionnaire, with 10 items to address behavioural adaptations to low blood sugars, and a 13 item 'Worry' scale to assess the concerns these patients have. The HFS has been used in other diabetes specific questionnaires to assess the impact of new treatment options (e.g., insulin lispro) (Shen et al., 1999), and considerable evidence exists which support its reliability and validity (Irvine et al., 1994).

The HFS scale contains 23 items on a 5-point likert scale. Total HFS score can be calculated by adding all 23 items; worry (HFSW) and behaviour (HFSB) subscales are the sum of their respective items. The HFS is scaled to reflect the respondent's greater fear (worry/behaviors) of hypoglycemia with higher scores.

3.3.3 RAND-12

For this study, self-reported health status was captured on the RAND-12 Health Status Inventory (HSI). The RAND-12 uses an alternate scoring algorithm to the Medical Outcomes Study Short Form 12-item Health Survey (SF-12), a previously developed and tested brief measure of health status (Ware et al., 1998). The SF-12 has become one of the most widely used instruments for the purposes of monitoring the health of both general and specific populations (Ware et al., 1998). Scores from the SF-12 closely reflect scores from the 36-item version (SF-36), although they do have less precision (Johnson & Pickard, 1998).

The RAND-12 measures the physical (PHS) and the mental (MHS) dimensions of HRQOL. The PHS and MHS are norm-based standardized scores, with a mean of 50 and standard deviation of 10 (i.e. T-Scores) in the general United States Population (Hays, 1998). The higher the respective summary score, the better the subjects health status,

The use of the RAND-12 in this study was justified by the context of which the study was carried out. This was the first phase of a study designed to evaluate the provision of free diabetic supplies to the population. Global measures, such as the RAND-12, would be required to assist in the decision making process in assessing the effectiveness of a policy to provide free testing supplies to those with type 2 diabetes. For this study which looks at the cross-sectional baseline data, health status was used to a) see if there was any relation of health status with HbA1c, and b) as a control variable in the multivariate analyses. Inclusion of disease specific measure was excluded in order to keep the overall questionnaire brief in order to reduce response burden.

3.3.4 EBAS

Perceived barriers to SMBG were assessed with one subscale of the EBAS. The EBAS measures a total of 60 barriers across four areas of self-care behavior (i.e., diet, exercise, blood glucose testing, and medication.). The EBAS blood glucose testing subscale ($\text{EBAS}_{\text{SMBG}}$) that was used in this baseline study consists of 13 questions assessing barriers to SMBG. Respondents answer on a 5-point Likert type scale that ranges from Never to Always. Respondents are also presented with a sixth option of Not Applicable. Scores for the subscale are calculated by summing the responses to all of the items. Higher scores reflect the subject's greater perceived barriers to SMBG testing.

Individual items were also used to determine the effect of a specific barrier on SMBG correlates. One item of interest in the questionnaire is the extent that the cost of supplies kept patients from testing their blood sugars as they think they should.

The internal consistency of the total scale was 0.94 in a sample of 217 subjects with both type 1 and type 2 diabetes (Irvine et al., 1990). The internal consistency reliability coefficient for the blood glucose subscale has been reported to be 0.86. Inclusion of this measure into the study will enable the exploration of the relationships between environmental barriers to SMBG and any clinical or behavioral factors.

3.3.5 Insurance

Pharmacists assessed patients' insurance status at the initial study visit. Patients were asked if they had any type of insurance coverage, either personal or coverage through employment, which covered SMBG test strips. The type of insurance coverage of diabetes test strips, for example reimbursement, co-payments, and deductibles, were not recorded.

3.3.6 Clinical

Clinical information was collected as part of the self-administered survey (Appendix 2). Variables included duration of diabetes, history of high blood pressure, history of high cholesterol, vision problems, cataracts, kidney disease, foot problems, amputations, and nerve disease. Patients were also asked, via the self-administered questionnaire, to recall over a six month period then number of times they have seen a doctor in general, and also specifically for diabetes. Attendance at a diabetes education clinical and years since the last visit to a diabetes educational clinical was requested to determine if these influenced any correlates of blood glucose control.

Baseline HbA1c was measured through the central regional laboratory in each of the three cities. Methodologies were of each city was compared, and ten samples from laboratories with differing methodologies were compared against each other. The Intraclass Correlation Coefficient (ICC) was used as an index of reliability of the different HbA1c methodologies. The rater factor will be treated as a fixed factor in a two way mixed model (Nichols, 1998). Systematic differences among levels of ratings will be considered relevant with measures of absolute agreement being produced.

Patients were asked via the self-report questionnaire if they had experienced any episodes of minor or severe hypoglycemia over a 3 month period. Minor hypoglycemia was defined as experiencing low blood sugars that the patient was able to treat by themselves without help. Severe hypoglycemia was defined as experiencing low blood sugars that required help by another person or going to the hospital to treat.

3.4.0 Data Analysis

All hypotheses were evaluated initially with bivariate correlational analyses. Pearson's R or Spearman's rho was used, depending on the distribution of the scores and the level of measurement (i.e., ordinal or interval) of the scores themselves. Multiple regression was carried out for hypothesis 5 and 6, with each variable blocked into the analysis. All hypotheses were assed using two-sided tests of significance at conventional levels of alpha = 0.05. Data was analyzed using SPSS statistical analysis package v11.9 (SPSS 2002).

3.4.1 Descriptive Statistics

Variables used to characterize the sample included age, gender, education level, marital status, annual income, duration of diabetes, treatment of diabetes, attendance at a diabetes educational clinic, co-morbidities (retinopathy, neuropathy, nephropathy, cardiovascular disease, foot problems, amputations). All descriptive characteristics were collected by self-reported survey completed by the patients at there own convenience which they mailed back to the study center. At the pharmacy, requisitions for HbA1c were given to the patients along with instructions to proceed to the local lab. The patients' clinical glycemic status was then was assessed from the HbA1c obtain from the central laboratories in each city.

3.4.2 Bivariate Analysis

Hypotheses:

1) Subjects with low adherence to SMBG will have poorer glycemic control, as measured by HbA1c.

- Predict medium negative correlation between the two variables.

The hypothesis predicts that subjects who test less frequently in the last 7 days have poorer glycemic control compared to those who have tested more frequently in the last 7 days. Therefore, a negative correlation is predicted between SMBG when compared with HbA1c.

In Fontbonne's prospective trial (Fontbonne et al., 1989), subjects were found to have better metabolic outcomes with the use of more blood strips ($r=0.36$, $p<0.02$). Based on this correlation, it is predicited that SMBG and HbA1c will have a medium ($r=0.30$) correlation.

2) Subjects with greater fear of hypoglycemia will have poorer glycemic control, as measured by HbA1c.

- Predict small positive correlation between both the worry and behavior subscales with HbA1c.

Irvine and colleagues found no significant correlation between the HFS and HbA1c (Bradley, 1994) for persons with type 1 and type 2 diabetes on insulin. Likewise, Polonsky and colleagues did not find a significant correlation between HFS and HbA1c (Polonsky et al., 1992). Despite these results, we felt it important to further test this relationship in the context of our sample of patients with type 2 diabetes not on insulin.

Initial thoughts on the relation between fear and hypoglycemia was of a linear model of: Hypoglycemia → Fear (Worry) → Avoidance Behavior → Elevated BG level (Bradley, 1994.) However, the relationship appears to be influenced by a variety of factors such as the risk and degree of distress caused by the episodes of hypoglycemia, psychological predisposition toward anxiety, and adequacy of the self-care response.

3) Subjects with worse self-reported health status will have poorer glycemic control, as measured by HbA1c.

- Predict medium negative correlation both physical and mental health summary scores of the RAND-12 and this should have a negative relationship with the subjects HbA1c.

In using a regression analysis to predict glycosylated hemoglobin from SF-36 scores, Anderson and co-workers reported non-significant correlations of r=0.17 to 0.32 for those with type 2 diabetes for those not on insulin and those on insulin respectively. Others have reported similar results (Maddigan et al., 2002), but some reports indicate a strong relationship between glycemic control and health status (Testa et al., 1998).

4) Subjects with greater self-perceived barriers to SMBG testing will have poorer glycemic control, as measured by HbA1c.

- Predict medium positive correlation

Irvine et al. (1990) reported a small correlation (r=0.28) between the total EBAS scale and HbA1c. The authors reported the results for both insulin and non-insulin dependent diabetes. We expected a similar relationship, particularly for the specific EBAS subscale for barriers to SMBG.

3.4.3 Multivariate Hypotheses

In order to account for potential confounding due to demographic, clinical, and HRQOL factors, multivariate models were used for hypotheses 5 and 6.

Additional analyses included multivariate linear regression analyses to evaluate the hypothesized relationships after controlling for demographic (e.g., age, gender) and clinical (e.g., duration of diabetes) variables.

The multivariate model (Table 3.1) will be used to test hypothesis number five.

Table 3.1: Hypothesis 5 in the Multivariate Analysis

H_o	Null Hypothesis:	There is no difference in relationship of the glucose testing subscale in the SDSCA ($SDSCA_{Gluc}$) and the EBAS while controlling for HbA1c
H_A	Alternate Hypothesis:	There is a difference in the relationship between $SDSCA_{gluc}$ and the EBAS. The relationship is stronger for those with higher HbA1c, then for those with lower HbA1c.

Table 3.2 Proposed multivariate model for Hypothesis 5

$$\{SDSCA\}_{Gluc.\ Test} = \alpha + \{EBAS\} + \{HbA1c\} + \{EBAS \times HbA1c\} + \{Clinical\} + \{demo\} + \{HRQL\} + \varepsilon$$

Where:

HbA1c:	= Hemoglobin A1c
Clinical:	= Clinical Factors • History of hypoglycemia -minor hypoglycemia -severe hypoglycemia • Duration of Diabetes • Use of Oral medication for blood glucose control
Demo:	= Demographics • Age (years) • Sex • Education Level (High School Completed) • Income (> $40,000 household income) • Marital Status (Married/living with partner) • Insurance that covers SMBG test strips
HRQL:	= Health Related Quality of Life • MHS • PHS
ε:	= Error • Variance not accounted for in the model

Table 3.3 Hypothesis 6 in the Multivariate Analysis.

H_0 -6	Null Hypothesis:	There is no differences in the relationship between the DV and IV in hypotheses one through four between those with insurance that covers SMBG test strips and those without insurance that covers SMBG test strips.
H_A -6	Alternate Hypothesis:	There is a difference in the relationship between the DV and IV in hypotheses one through four between those with insurance that covers SMBG test strips and those without insurance that covers SMBG test strips.

Where: DV = HbA1c and IV = SMBG, HFS, HRQL, EBAS

Table 3.4 Proposed Multivariate Model for Hypothesis 6.

$$DV = \alpha + \{IV\} + \{clinical\} + \{demo\} + (insurance \times IV) + (insurance) + \varepsilon$$

Where:

Clinical:	= Clinical Factors - History of hypoglycemia - Number of Medications - Duration of Diabetes
Demo:	= Demographics - Age (years) - Gender - Education Level - Income - Marital Status
Insurance:	- Yes or No to insurance that covers SMBG testing strips
ε:	= error - Variance not accounted for in the model

3.5 Sample size considerations

A priori calculations for sample size were carried out using Cohen's convention of effect size (ES) (Table 3.5 & Table 3.6) (Cohen, 1988). The ES index is simply r, the population product-moment correlation coefficient. Two-tailed tests were used with a significance criterion of $\alpha = 0.05$ and a power of 0.80. Power of 0.80 is also a convention set by Cohen whenever an investigator cannot find a basis to choose a value *ad hoc* in their specific investigation.

In order to have sufficient power to detect a small ES of $r=0.10$ with an $\alpha = 0.05$ the study required a sample size of $n=800$ (Table 3.5). Sufficient power to detect a medium ES of $r=0.30$ was achievable with $n=84$ sample size. 726 additional subjects would have to been recruited to achieve the incremental gain in ES. Table 3.6 is a summary of scenarios showing the incremental gain in power with sample size for the small and medium effect size.

Table 3.5 Effect Size (ES) relationship with correlation (r) and sample size (n) calculations ($\alpha = 0.05$; power = 0.80).

ES	r	n (each group)
Small	0.10	800
Medium	0.30	84
Large	0.50	28

Table 3.6 Power (p) table for sample size (n) and ES (r).

ES (r)	n	p
Small (0.10)	84	15
Medium (0.30)	84	80
Small (0.10)	100	17
Medium (0.30)	100	86
Small (0.10)	140	22
Medium (0.30)	140	95
Small (0.10)	200	29
Medium (0.30)	200	99
Small (0.10)	300	41

3.6 Ethical Considerations

Ethics approval for the study was obtained from the University of Alberta Health Research Ethics Board Panel B (Appendix 3) and by the Regina Health District Research Ethics Board. Subjects received a study information sheet outlining the purpose, procedures, risks & benefits, confidentiality, and outlined the freedom to withdraw from the study. Written consent was obtained from the participants (Appendix 1). Participant confidentiality was maintained by assigned individual study IDs with the recruiting pharmacist being the only individual able to decode these numbers.

3.7 Summary

This was a cross-sectional study that utilized the baseline data from the first 200 patients that completed a survey and blood work for enrollment into a prospective, randomized, control trial. Patients 30 years of age and older, not on insulin, and had type 2 diabetes diagnosed for more than 1 year pre-enrolment were eligible for inclusion. Those with First Nations status were not included in the study since they have coverage for SMBG testing supplies on their federal drug plan.

Patients that volunteered for the study were recruited through a network of community pharmacies. They were provided with a questionnaire to complete and mail in at their own convenience, and were instructed to go to the nearest laboratory in order to provide a blood sample for HbA1c analysis. In addition to demographic and clinical information questions, four self-report instruments were included on the questionnaire. These instruments were the SDSCA, EBAS, RAND-12, and HFS.

Overall, 84 subjects was determined to provide adequate power to detect a medium effect size for the correlational analysis. To detect differences between those who had third party insurance covering SMBG testing supplies and those who did not have such insurance, as outlined in hypothesis 6, 162 subjects would have been required. This allowed us to sufficient power to detect significant differences between a large ES and a small ES between groups. To account for possible missing data, we inflated the sample size to 200 subjects with completed laboratory results and returned surveys.

Data analysis was initially carried out with bivariate correlational analysis. Multiple regression was carried out for hypotheses 5 and 6. The results of these analyses are reported in the next chapter.

Chapter 4

Results

This chapter will present the results of a cross-sectional study that utilized the baseline data that was gathered from a prospective, randomized, control trial. Initially, participant demographics will be used to characterize the study sample. Correlational analysis was carried out for hypothesis 1 through 4. Hypothesis 5 was tested using multivariate linear regression analysis. For hypothesis 6, multivaritate linear regression was also used to test the effect that insurance for SMBG testing strips has on HbA1c, while controlling for demographic and clinical variables.

4.1.0 Study Sample

4.1.1 Patient Demographics

Baseline survey data and HbA1c results were used from the first two hundred patients that who were enrolled in a RCT from December 2001 to July 2002, had returned a survey and had a HbA1c measurement preformed. Tables 4.1 through Table 4.3 and Figure 4.1 summarize the demographic information, HbA1c, oral medication for diabetes, and additional variables collected to characterize the study sample at entry into the RCT.

The patients' average age was 63.6 years (SD 10.3), with 54.8% males. The range of ages was from 35 to 84 years old. Patients responded that they had diabetes for an average of 8.0 years with a standard deviation (SD) of 7.2 (range 1- 42 years). The majority (76.9%) of the patients had previously been to a diabetes education clinic at a mean of 4.1 (SD 4.4) years ago. The majority of patients completed high school (65.2%)

and had a median income in the $20,000 to $39,999 range. Further demographic information of the patients is provided in Table 4.1.

Table 4.1 Baseline Demographics (n=200).

Gender (%male)	54.8%
Age	63.6 (10.3)
Duration of diabetes	8.0 years (7,2)
HbA1c	7.2% (1.17%)
Household income:	(median $20k -$39k)
<$40,000	53.8%
≥$40,000	46.2%
Education (High school)	65.2%
Martial Status	
Married/living together	68.8%
Single/divorced/Widowed	31.2%
Attended Diabetes Education Clinic? (%yes)	(76.9%)
Years since last visit?	4.1 (4.4)
Number of times you have seen the doctor in the last six months?	4.6 (4.3)
Number of times in the last six months you have seen the doctor for diabetes?	2.4 (2.0)
In the last three months, have you experienced low blood sugars that:	
a) You were able to treat yourself without help? (%Yes)	39.7%
b) You needed help by another person or you went to the hospital to treat? (%Yes)	4.0%
Medical conditions due to diabetes:	
Vision problems	24.6%
Cataracts	13.1%
Kidney disease	3.0%
Foot problems	21.1%
Amputations	1.0%
Nerve Disease	7.5%
Mean Body Mass Index (SD)	30.5 (7.1)

4.1.2 Glycemic Control

The original sample of patients (n=200) presented with HbA1c values ranging from 4.7 to 14.3% with a mean HbA1c of 7.2% (SD 1.2%). The patient with an HbA1c value of 14.3% was considered an outlier and excluded from the sample, however, this had no significant effects on the subsequent analysis. For the remainder of the sample (n=199), the HbA1c values ranged from 4.7% to 11.6% with a mean of 7.2% (SD 1.2%) (Figure 4.1).

The HbA1c values had a slight positively skewed distribution (skewness = 1.09) (Figure 4.1). When subjects were classified according to levels of glucose control according to CDA-CPGs (Meltzner et al., 1998) 24 subjects (12.1%) had ideal (normal nondiabetic) HbA1c values and 80 patients (40.2%) had Optimal (Target goal) HbA1c values. Seventy one subjects (35.7%) and 24 subjects (12.1%) had suboptimal (Action may be required) and Inadequate (Action required) control, respectively (Table 4.2). The majority of the patients (96.5%) were on an oral medication for their diabetes.

Figure 4.1 Distribution of HbA1c values.

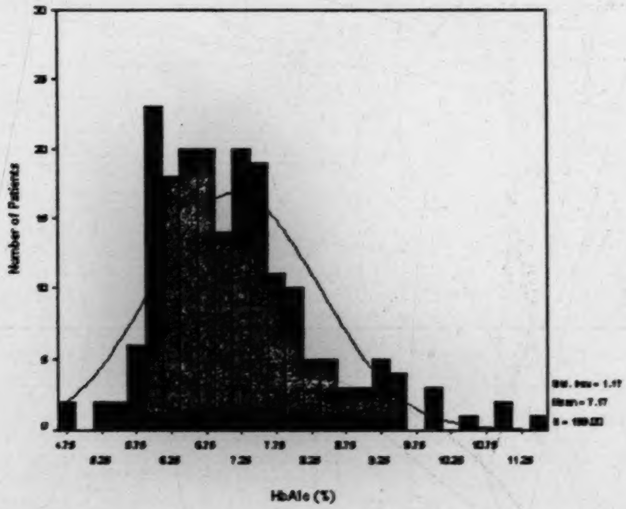


Table 4.2 Levels of blood glucose control based on CDA-CPG.

Ideal 4-6% HbA1c (normal nondiabetic)	12.1% (n = 24)
Optimal <7.0% HbA1c (target goal)	40.2% (n = 80)
Suboptimal 7.0 – 8.4% HbA1c (action may be required)	35.7% (n = 71)
Inadequate >8.4% HbA1c (action required)	12.1% (n = 24)

There was approximately an even number of patients that had their HbA1c samples analyzed with one of two methodologies. A sample of 10 patients had their HbA1c analyzed under both methodologies in order to calculate the ICC. The mean difference, for this sample, between the two laboratory methods was approximate 0.26% (SD=0.26). The ICC was found to be 0.77. When the ICC was calculated based on stratification into levels of blood glucose, the ICC on the reliability among the level of ratings was 0.90.

4.2 Analysis of Primary Hypotheses

4.2.1 Adherence to SMBG

Frequency of self-reported SMBG in the past 7 days was measured by the SDSCA question "On how many of the last SEVEN DAYS did you test your blood sugar?". 196 patients responded that they tested their blood sugars a mean of 4.1(SD 2.41) days over a 7 day period, with responses ranging from 0 to 7 days. Almost one third (28.1%) of the patients responded that they tested their blood sugars on a daily basis, compared to 10.6% who reported that they did not test their blood sugar at all in the last 7 days (Table 4.3).

Table 4.3 Self-reported frequencies of the number of days blood glucose was tested in the last 7 days.

Number of days tested blood sugars in the last 7 days	Number of subjects (%)
0	21 (10.6%)
1	11 (5.5%)
2	21 (10.6%)
3	37 (18.6%)
4	22 (11.1%)
5	14 (7%)
6	14 (7%)
7	56 (28.1%)

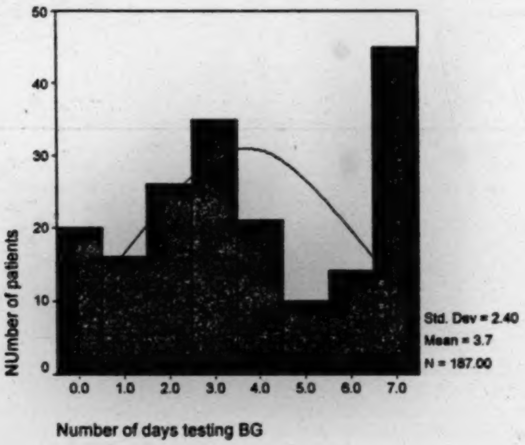
For those responding to how many days did they test as recommended by their health care provider (n=186), the mean response was 3.3 days (SD 2.7) with responses ranging from 0 to 7 days. About one quarter (23.1%) of the patients reported that they tested every day of the week according to the recommendations from their health care provider. Similarly, one quarter (25%) of the patients reported that they did not test their blood glucose (as recommended) on any of the last 7 days (Table 4.4).

Table 4.4 Frequencies of responses for the question "On how many of the last SEVEN DAYS did you test your blood sugar the number of times recommended by your health care provider?"

Number of days tested blood sugars in the last 7 days as recommended by health care professional	Number of subjects (%)
0	50 (25.1%)
1	10 (5%)
2	18 (9%)
3	27 (13.6%)
4	19 (9.5%)
5	9 (4.5%)
6	7 (3.5%)
7	46 (23.1%)

Overall adherence to SMBG was measured by the mean of the two blood glucose testing questions in the SDSCA. There were 187 patients (98.5%) that had complete data for the two questions on blood glucose testing on the SDSCA. Mean average scores of both questions ranged from 0.0 to 7.0 with a mean of 3.7 and standard deviation of 2.4. The distribution of SDSCA scores (Figure 4.2) shows the scores were evenly distributed (skewness = 0.084) over most of the distribution, therefore Pearson's correlations was used for the correlational analysis.

Figure 4.2 Distribution of mean SDSCA blood sugar testing scores.

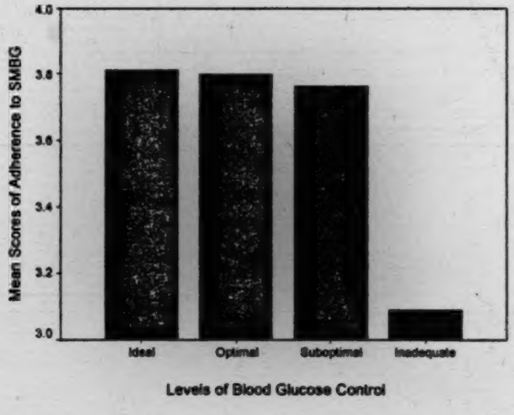


Hypothesis 1: Subjects with low adherence to SMBG will have poorer glycemic control, as measured by HbA1c.

- ☐ Predicted medium negative correlation between the two variables

Patients were initially stratified based on their HbA1c values into levels of blood glucose control (Figure 4.3). There was no significant differences in the mean scores of adherence to SMBG by level of BG control (p = 0.656).

Figure 4.3 Mean scores of Adherence to SMBG by levels of BG control.



The overall correlation for all levels of blood glucose control and the mean of the SDSCA blood glucose testing scores was -0.054 (p=0.468) (Figure 4.4). Correlations ranged from -0.044 (p=0.726) for those with suboptimal control to 0.255 (p<0.05) for those with an optimal level of BG control (Table 4.5). When subjects reporting 100% adherence (i.e. SDSCA BG testing score = 7.0 days) were excluded, the relationship between HbA1c and SMBG adherence remains small (r=-0.022) and nonsignificant (p=794).

Figure 4.4 Correlation between SDSCA & HbA1c (r=-0.044, p = 0.726).

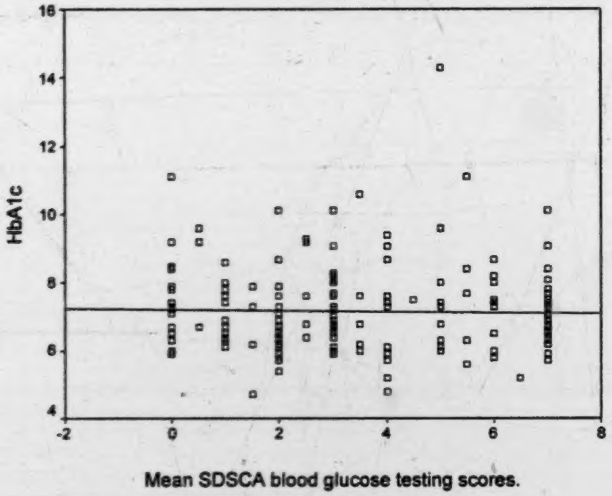


Table 4.5 Relationship between HbA1c and mean SDSCA blood glucose testing scores.

Level of blood glucose control	Pearson's Correlation (p)
Ideal (n = 24)	-0.012 (p = 0.955)
Optimal (n = 80)	0.255 (p = 0.028)*
Suboptimal (n = 71)	-0.044 (p = 0.726)
Inadequate (n = 24)	0.107 (p = 0.645)
All levels (n = 199)	**-0.054 (p = 0.468)**

Those with optimal and inadequate BG control had an association that was counter to the hypothesized direction. There was a significant positive correlation (r=0.26; p=0.03) between HbA1c and SDSCA BG monitoring score those who had optimal control. The direction of this correlation implies that those who have HbA1c values between 6% and 7% test more frequently and more in accordance with their health care professional's recommendations have poorer control (i.e. higher HbA1c). Patients classified as having an inadequate level of BG control had a non-significant positive (r=0.107; p=0.645) association between BG testing scores and HbA1c.

4.2.2 Fear of Hypoglycemia

The HFS contains 23 items of a 5-point Likert scale. The total HFS score was calculated by adding all 23 items. The HFS is scaled to reflect the respondents' fear of hypoglycemia. The higher the fear of hypoglycemia, the greater the score (range 0 – 92).

Patients' scores of the HFS in our sample ranged from 0 – 63, with a mean of 12.8 (SD 14.3). The distribution of total scores was positively skewed (skewness = 1.5; figure 4.5). There were HFS total scores for 124 patients (62%). The worry subscale of the HFS (HFSW) had a mean score of 6.3 (SD 9.6) with a range of 0 to 45. The behaviour subscale (HFSB) had a mean score of 7.1 (SD 7.0) with a range of 0 to 58. Distributions of both the HFSB and HFSW were positively skewed (Figure 4.6 and 4.7 respectively); Spearman's rho correlations was therefore used for the analysis with HFS scores.

Figure 4.5 Distributions of total HFS scores. (Skewness = 1.5)

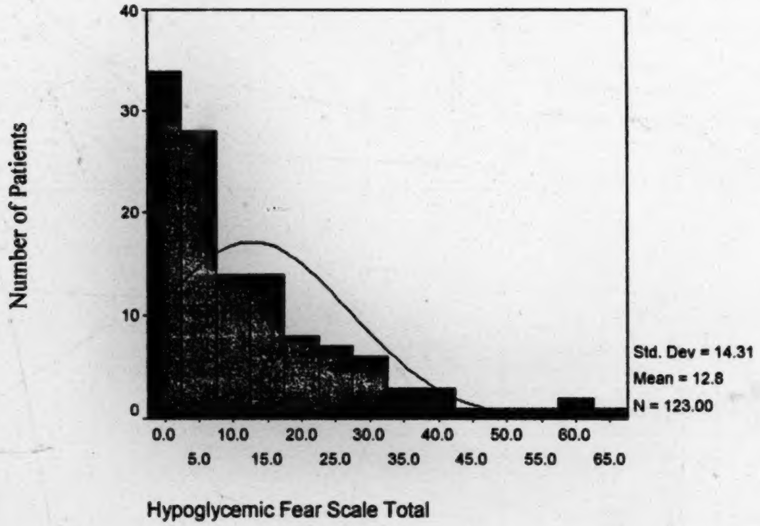


Figure 4.6 Behavior Subscale of the Hypoglycemic Fear Scale (Skewness = 1.3)

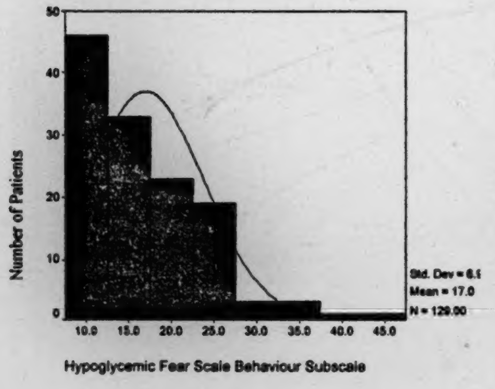
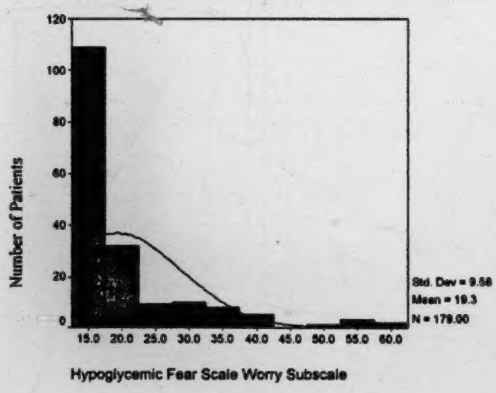


Figure 4.7 Worry Subscale of the Hypoglycemia Fear Scale (Skewness = 2.2)



Hypothesis 2: Subjects with greater fear of hypoglycemia will have poorer glycemic control, as measured by HbA1c.

- ☐ Predict small positive correlation between both HFS worry and behaviour subscale with HbA1c.

There was a small negative correlation between HbA1c and the total score for the HFS that was non-significant (r = -0.036; p=0.290). The worry subscale had a non-significant correlation with HbA1c (r =-0.057; p = 0.450). The correlation between HbA1c and the behavioural subscale was r = 0.010 and also non-significant (p = 0.910).

Correlations by level of blood glucose control (Table 4.6) ranged from (rho = -0.054) for those with a suboptimal level of glycemic control to rho = 0.248 for those with an inadequate level of glycemic control. None of the correlations were significant.

Table 4.6 Correlations between HbA1c and total HFS score.

Level of blood glucose control	Spearman's rho Correlation (p)
Ideal	0.152 (p = 0.589)
Optimal	-0.066 (p = 0.648)
Suboptimal	-0.054 (p = 0.736)
Inadequate	0.177 (p = 0.496)
All levels	**0.036 (p = 0.691)**

4.2.3 Health Status

The RAND-12 provides two summary scores for physical (PHS) and mental health (MHS). The higher the summary score, the better the subjects' health status. Both scores are calculated as T-scores, with mean scores of 50.0 and SD of 10.0 in the normed population (Hays, 1998).

The mean PHS score was 44.6 with a standard deviation of 10.6 (n = 200). For the MHS, the mean was 45.4 (SD 11.4) with 198 of the respondents completing the measurement. The distributions of the PHS and MHS are shown in Figures 4.8 and 4.9 respectively. Both the PHS and MHS scores were normally distributed (skewness = -0.366 and -0.475 respectively), therefore, the parametric test Pearson's r was used for the analyses of the correlations in hypothesis 3.

Figure 4.8 Distribution of PHS scores.

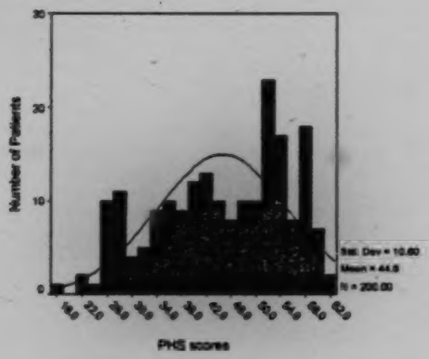
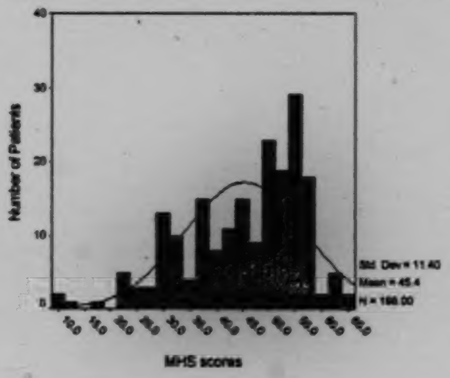


Figure 4.9 Distributions of MHS scores.



Hypothesis 3: Subjects with worse self-reported health status will have poorer glycemic control, as measured by HbA1c.

- ☐ Predict medium negative correlation both subscales (MHS and PHS) of the RAND-12

The correlation between MHS and HbA1c (Figure 4.10) was small and positive (r = 0.06) correlation but was not significant (p = 0.417). Likewise for the PHS scores correlated with HbA1c (Figure 4.11), there was a non significant positive correlation (r = 0.12; p = 0.095).

Figure 4.10 Correlation between MHS and HbA1c (r = 0.06; p >0.05).

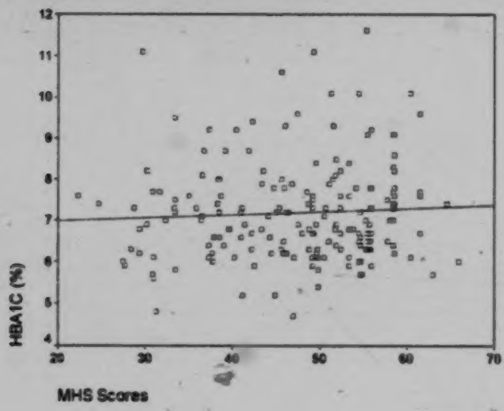
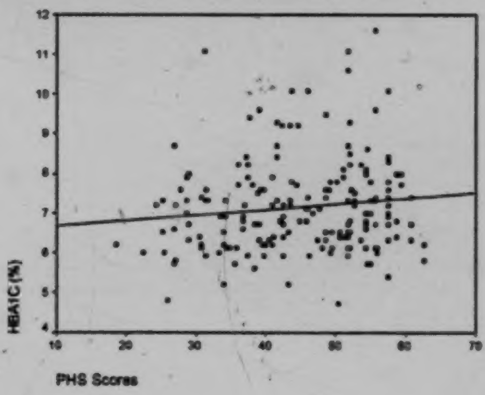


Figure 4.11 Correlation between PHS and HbA1c (r = 0.12; p > 0.05).



When the MHS and PHS were correlated with HbA1c stratified by levels of blood glucose control, there were no significant relationships (Table 4.7 & Table 4.8).

Table 4.7 Relationship between HbA1c and MHS.

Level of blood glucose control	Pearson's Correlation (p)
Ideal	0.187 (p = 0.406)
Optimal	0.012 (p = 0.917)
Suboptimal	0.106 (p = 0.395)
Inadequate	-0.006 (p = 0.977)
All levels	**0.060 (p = 0.417)**

Table 4.8 Relationship between HbA1c and PHS.

Level of blood glucose control	Pearson's Correlation (p)
Ideal	-0.075 (p = 0.728)
Optimal	0.068 (p = 0.552)
Suboptimal	0.163 (p = 0.184)
Inadequate	0.147 (p = 0.525)
All levels	**0.121 (p = 0.095)**

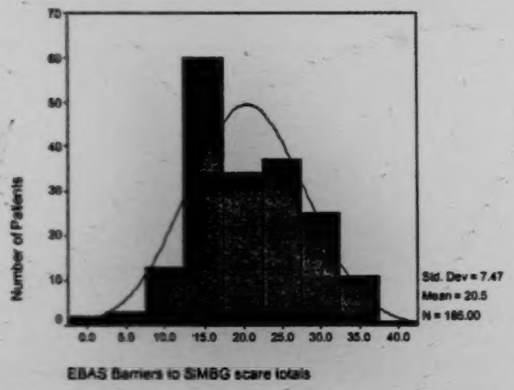
4.2.4 Self-perceived barriers to SMBG

The blood glucose testing subscale of the EBAS was used to measure self-perceived barriers to SMBG testing. The measurement consists of 12 questions, with a 5-point Likert response options, with a 6th option of not applicable. The EBAS subscale was scored by summing the responses for an overall score. Higher scores reflected greater perceived barriers to SMBG testing.

The total SMBG barriers scores were normally distributed (skewness = 0.164) (Figure 4.12), therefore Pearson's correlations was used for the analysis of hypothesis 4.

Completed EBAS blood glucose subscales were available for 186 subjects for the analysis. The mean score was 20.5 with a standard deviation of 7.47.

Figure 4.12 Distributions of EBAS scores.



Hypothesis 4: Subjects with greater self-perceived barriers to SMBG testing will have poorer glycemic control, as measured by HbA1c.

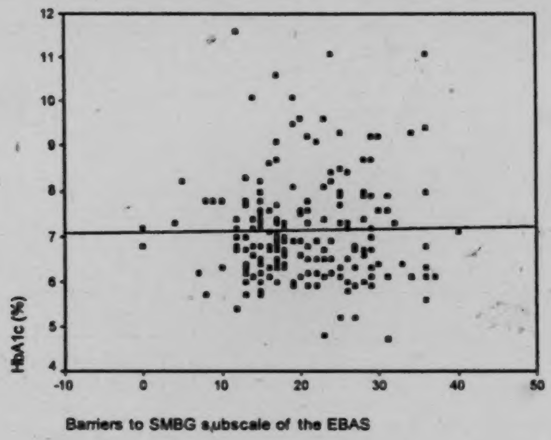
- ☐ Predict medium positive correlation between HbA1c and EBAS-BG scores

The overall correlation between HbA1c and the EBAS subscale was 0.017 (p = 0.815)(Figure 4.13). Correlations ranged from -0.26 (p = 0.23) to 0.157 (p = 0.49) for those with ideal levels of blood glucose and those with inadequate levels of blood glucose control, respectively. None of the correlations were significant (Table 4.9).

Table 4.9 Correlations of HbA1c with the EBAS blood glucose subscale.

Level of blood glucose control	Pearson's Correlation (p)
Ideal	-0.262 (p = 0.228)
Optimal	-0.219 (p = 0.054)
Suboptimal	0.064 (p = 0.617)
Inadequate	0.157 (p = 0.485)
All levels	**0.017 (p = 0.815)**

Figure 4.13 Correlation of EBAS barriers to SMBG subscale and HbA1c.



4.2.5 Barriers and Adherence to SMBG

The multivariate model (Table 3.1) was used to test the following hypothesis regarding the relationship between the adherence to SMBG (SDSCA $_{SMBG}$) and barriers to SMBG (EBAS). The null hypothesis states that there is no difference in relationship of the glucose testing subscale in the SDSCA (SDSCA$_{SMBG}$) and the EBAS while controlling for HbA1c.

Because of missing data for the variables in the model, the multivariate analysis used a sample size of 156 subjects. The overall model was found to be not significant ($r^2 = 0.108$, $p = 0.330$). There were no statistically significant relationships between EBAS and SDSCA glucose scores after controlling for HbA1c, history of hypoglycemia, duration of diabetes, insurance that covers SMBG supplies, income, marital status and health status. The interaction terms were not significant.

Table 4.10 shows the relationships between the SDSCA glucose scores and the independent variables. While the overall model was not significant, the independent variable of self reported history of at least one episode of minor hypoglycemia in the last 3 months that did not require the help of a third party was significant ($\beta = 0.176$; $p = 0.041$). The positive coefficient would indicate that those with a history of minor hypoglycemia would be more adherent to testing their blood glucose. All other factors were not significantly associated with adherence to SMBG.

Table 4.10 Model of coefficients for hypothesis number 5.

	Unstandardized Coefficients		Standardized Coefficients		
	B	Std. Error	Beta	t	Sig.
(Constant)	1.584	4.845		.327	.744
Insurance for strips	-.479	.462	-.100	-1.038	.301
Duration of DM	-2.62E-02	.033	-.075	-.804	.423
Minor hypoglycemia	1.003	.432	.207	2.323	.022
Severe hypoglycemia	.392	1.307	.027	.300	.765
Oral agents for DM	.565	1.809	.028	.313	.755
Age in Years	-2.15E-02	.025	-.094	-.864	.389
Sex	-.821	.435	-.171	-1.886	.062
High school education	-.577	.461	-.113	-1.252	.213
Income	.303	.491	.063	.616	.539
Married or living with partner	.852	.485	.163	1.758	.081
HBA1C	.793	.605	.376	1.311	.192
EBAS	.191	.176	.609	1.090	.278
EBASxHbA1c interaction	-3.73E-02	.025	-.960	-1.508	.134
MHS	-1.71E-03	.026	-.006	-.066	.947
PHS	8.597E-04	.023	.004	.037	.971

4.2.6 Insurance Coverage and Correlates of Glycemic Control

4.2.6.1 Insurance Coverage

One half (51.0%) of patients had coverage for SMBG testing strips through private or public insurance. Overall, those with insurance that covers SMBG testing strips had a significantly lower HbA1c as compared to those without insurance that covers blood glucose testing strips (7.0% HbA1c vs. 7.4% respectively (p= 0.024). This significant difference in HbA1c values was not seen when individuals were stratified based upon the CPG-CDA but the largest difference appeared to be among individuals with the poorest glycemic control (i.e. HbA1c > 8.4%) (Table 4.11).

Table 4.11 Differences in HbA1c for those with insurance that cover SMBG testing strips vs. those without insurance.

Level of blood glucose control (HbA1c %)	Mean HbA1c (SD) without insurance	Mean HbA1c (SD) with insurance	Difference in HbA1c (Significance)
Ideal (4-6)	5.6% (0.48) n = 6	5.7% (0.34) n = 18	0.1% (p = 0.368)
Optimal (6-7)	6.6% (0.28) n = 42	6.5% (0.29) n = 38	0.1% (p = 0.890)
Suboptimal (7-8.4)	7.6% (0.30) n = 32	7.7% (0.40) n = 39	0.1% (p = 0.052)
Inadequate (>8.4)	9.9% (1.40) n = 18	9.4% (0.75) n = 7	0.5% (p = 0.556)
All levels	**7.4% (1.27) n = 98**	**7.0% (1.05) n = 102**	**0.4% (p = 0.024)**

Patients with insurance that covers SMBG testing strips also were significantly younger with a mean age of 60.2 years (SD 9.5), compared to those without insurance that covers SMBG testing strips (66.9 years; SD 10.0; p < 0.001)(Table 4.12). Those patients with insurance had a significantly higher income, with 53.9% of people with insurance having a household income greater than or equal to \$40,000 compared to 55% Likewise patients with insurance had self-reported that they attended a diabetes education clinic a mean of 3.3 years ago, compared with 4.9 years for those without insurance ($p = 0.031$). There were no significant differences in PHS or MHS between those with or without insurance for test strips. Body mass index and duration of diabetes were not significantly different between the two groups.

Table 4.12: Patient Characteristics based on insurance that covers SMBG testing strips vs. those without insurance.

Variable	With Insurance (SD)	Without Insurance (SD)	Significance
Age	60.2 (9.5)	66.9 (10.0)	$P<0.001$
Income ≥ \$40K	53.9%	38.1%	$P<0.05$
Education (High School)	45%	55%	$P > 0.05$
Duration of Diabetes	7.2 Years (6.5)	8.9 Years (7.7)	$P >0.05$
Years since last visit to diabetes educational clinic?	3.3 Years (3.0)	4.9 (5.4)	$P < 0.05$
Mean $\text{SDSCA}_{\text{GLUC}}$ Scores	4 (2.4)	3 (2.4)	$P > 0.05$
Number of times you have seen the doctor in the last six months?	4.81 (4.6)	4.38 (3.8)	$P > 0.05$
Number of times in the last six months you have seen the doctor for diabetes?	2.44 (4.0)	1.9 (2.9)	$P > 0.05$
Physical Health Status	44.2 (10.7)	44.9 (10.6)	$P>0.05$
Mental Health Status	46.1 (10.5)	44.7 (12.3)	$P>0.05$
Body Mass Index (BMI)	31.2 (7.6)	30.0 (6.5)	$P > 0.05$

Because of these differences in sociodemographic and clinical characteristics, the impact of insurance coverage for SMBG supplies on the relationships between glycemic control (i.e. HbA1c) and frequency of SMBG, fear of hypoglycemia, health related quality of life, and barriers to SMBG were also examined with multivariate analysis. The hypothesis tested was there were no differences in the relationship between HbA1c and the independent variables in hypotheses one through four between those with insurance that covers SMBG testing strips and those without insurance.

In all cases, the overall models were not statistically significant and the null hypotheses were not rejected for the independent variables stated in the proposed model (Table 4.13).

Table 4.13 Summary of Models tested in Hypothesis 6.

Independent Variable	n in model	R	R Squared	Sig.
SMBG	170	0.281	0.079	0.343
HFS	112	0.354	0.125	0.298
PHS	181	0.332	0.108	0.061
MHS	170	0.282	0.080	0.333
EBAS	168	0.329	0.108	0.104

4.2.6.2 Self-monitoring of Blood Glucose and Glycemic Control.

One hundred and seventy cases were included in the multivariate model that used SMBG as the IV. The overall model's multiple correlation was not significant with the coefficient (r) was 0.281 ($p = 0.343$). The proportion of variance in the DV accounted for by the model (r^2) was 0.079. There were no significant relationships between any of the IVs with the DV (Table 4.14). The interaction term between $\text{SDSCA}_{\text{SMBG}}$ and insurance was also non-significant.

Table 4.14: Model Coefficients for SMBG IV.

	Unstandardized Coefficients		Standardized Coefficients		
	B	Std. Error	Beta	t	Sig.
(Constant)	8.338	.954		8.738	.000
Insurance for strips	-.113	.337	-.049	-.334	.739
Duration of DM	1.583E-02	.014	.097	1.120	.264
Minor hypoglycemia	-.128	.188	-.056	-.684	.495
Severe hypoglycemia	.639	.461	.112	1.388	.167
Oral agents for DM	-.900	.707	-.104	-1.273	.205
Age in Years	-3.98E-03	.010	-.037	-.380	.704
Sex	-5.31E-02	.194	-.023	-.274	.785
High school education	.137	.199	.058	.691	.491
Income	-.128	.219	-.056	-.584	.560
Married or living with partner	-9.36E-02	.214	-.038	-.436	.663
Interaction term SMBG and Insurance	-4.01E-02	.075	-.093	-.538	.592
SMBG	6.106E-03	.054	.013	.113	.911

4.2.6.3 Fear of Hypoglycemia and Glycemic Control.

For the model involving Fear of Hypoglycemia total score, 112 patients were included in the multivariate model. Overall, the model was not significant (Table 4.15) with $r^2 = 0.125$ ($p = 0.298$). There were no significant relationships between any of the IVs with the DV. The interaction term between HFS and insurance was also non-significant.

Table 4.15: Model Coefficients for HFS IV.

	Unstandardized Coefficients		Standardized Coefficients		
	B	Std. Error	Beta	t	Sig.
(Constant)	8.183	1.577		5.189	.000
Insurance for strips	-.467	.877	-.199	-.532	.596
Duration of DM	1.500E-02	.021	.079	.731	.467
Minor hypoglycemia	1.100E-02	.257	.005	.043	.966
Severe hypoglycemia	.308	.745	.043	.413	.680
Oral agents for DM	-.889	1.222	-.072	-.728	.468
Age in Years	6.868E-03	.014	.060	.475	.636
Sex	-.244	.255	-.105	-.955	.342
High school education	-.109	.270	-.044	-.405	.686
Income	-.147	.290	-.063	-.507	.614
Married or living with partner	-.140	.276	-.054	-.508	.612
Interaction Term HFS and Insurance	2.707E-03	.018	.057	.153	.878
HFS	1.390E-02	.010	.172	1.462	.147

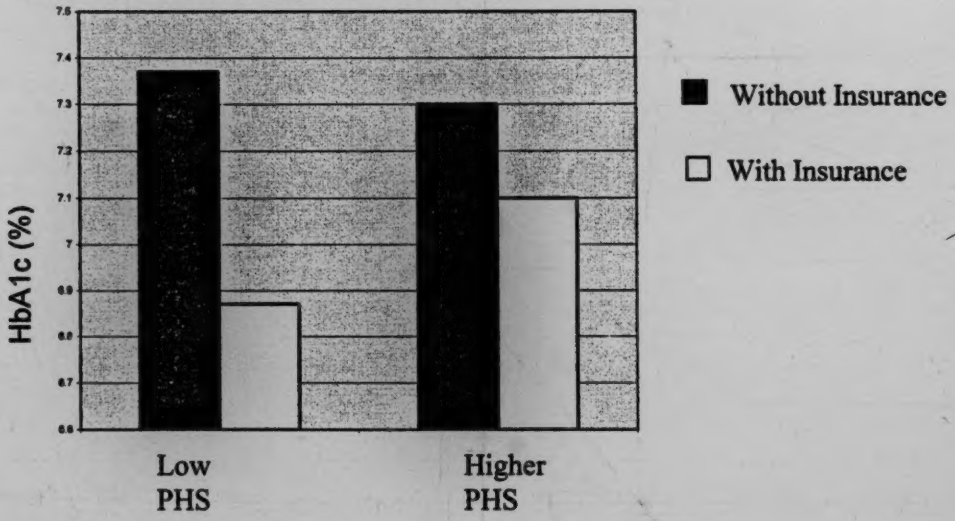
4.2.6.4 Physical Health and Glycemic Control.

There were 181 subjects included the multivariate model with PHS as the IV. The model was not significant ($r^2 = 0.110$; $p = 0.061$) when controlling for clinical and demographic variables. While the overall model was not significant, insurance coverage and the interaction between PHS and insurance were statistically significant (Table 4.16). The negative coefficient for insurance would indicate that those without insurance had a higher HbA1c; however, this depends on level of physical health. For subjects with poorer physical health and without insurance had the poorest glycemic control (Figure 4.14)

Table 4.16: Model coefficients for PHS IV.

	Unstandardized Coefficients		Standardized Coefficients		
	B	Std. Error	Beta	t	Sig.
(Constant)	9.000	1.064		8.460	.000
Insurance for strips	-2.292	.779	-1.026	-2.942	.004
Duration of DM	1.404E-02	.013	.092	1.053	.294
Minor hypoglycemia	-2.44E-02	.175	-.011	-.139	.890
Severe hypoglycemia	.805	.425	.151	1.894	.060
Oral agents for DM	-1.054	.582	-.142	-1.812	.072
Age in Years	-7.61E-03	.010	-.071	-.787	.433
Sex	-6.91E-02	.179	-.031	-.387	.699
High school education	.184	.192	.078	.961	.338
Income	1.174E-02	.203	.005	.058	.954
Married or living with partner	3.762E-02	.199	.016	.189	.850
Interaction Term PHS and Insurance	4.552E-02	.017	.956	2.672	.008
PHS	-1.18E-02	.013	-.109	-.932	.352

Figure 4.14 Comparison of HbA1c for those with and without insurance stratified based on median PHS.



4.2.6.5 Mental Health and Glycemic Control

For the model involving MHS, 170 patients were included in the multivariate model. Overall, the model was not significant with $r^2 = 0.080$ ($p = 0.333$). There were no significant relationships between any of the IVs with the DV (Table 4.17). The interaction term was also non-significant.

Table 4.17 Model Coefficients for MHS IV.

	Unstandardized Coefficients		Standardized Coefficients	t	Sig.
	B	Std. Error	Beta		
(Constant)	7.722	1.013		7.620	.000
Insurance for strips	-.402	.617	-.187	-.651	.516
Duration of DM	8.901E-03	.014	.058	.657	.512
Minor hypoglycemia	-2.10E-02	.178	-.010	-.118	.907
Severe hypoglycemia	.591	.476	.104	1.242	.216
Oral agents for DM	-.929	.582	-.134	-1.596	.113
Age in Years	3.818E-03	.010	.037	.380	.704
Sex	-5.87E-02	.186	-.027	-.315	.753
High school education	-4.59E-02	.194	-.020	-.237	.813
Income	6.625E-02	.207	.031	.320	.750
Married or living with partner	4.765E-02	.202	.020	.236	.814
Interaction term MHS and Insurance	-2.94E-03	.013	-.075	-.230	.818
MHS	9.651E-03	.023	.085	.420	.675

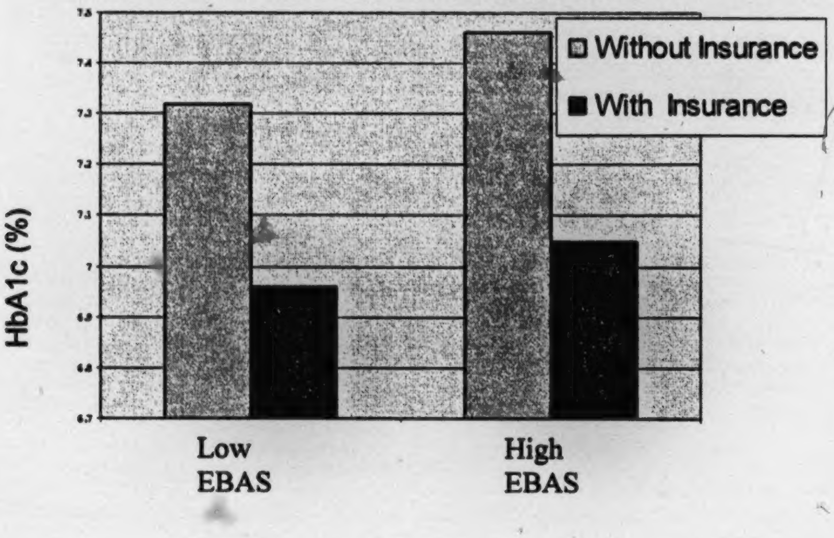
4.2.6.6 Barriers to SMBG and Glycemic Control.

The model involving EBAS, 168 patients were included. The overall model was not significant ($r^2 = 0.108$; $p = 0.104$). While the overall model was not significant, the EBAS and the interaction between EBAS and insurance were statistically significant (Table 4.18). However, since the interaction term of EBAS and insurance is significant, we are unable to interpret the results of the EBAS alone. In general, the greater the perceived barriers to SMBG, the poorer the glycemic control; particulary in subjects with out insurance coverage for SMBG supplies (Figure 4.15)

Table 4.18 Model Coefficients for EBAS IV.

	Unstandardized Coefficients		Standardized Coefficients		
	B	Std. Error	Beta	t	Sig.
(Constant)	7.451	1.120		6.655	.000
Insurance for strips	.793	.524	.354	1.513	.132
Duration of DM	1.463E-02	.014	.087	1.046	.297
Minor hypoglycemia	-.128	.186	-.056	-.686	.494
Severe hypoglycemia	.394	.579	.054	.680	.497
Oral agents for DM	-.985	.671	-.117	-1.469	.144
Age in Years	-2.28E-03	.011	-.021	-.214	.831
Sex	-4.97E-02	.186	-.022	-.268	.789
High school education	.177	.203	.074	.869	.386
Income	-9.96E-02	.213	-.044	-.468	.640
Married or living with partner	4.511E-02	.207	.019	.218	.827
EBAS	3.361E-02	.018	.227	1.836	.068
Interaction term EBAS and Insurance	-5.01E-02	.023	-.515	-2.140	.034

Figure 4.15 Comparison of HbA1c for those with and without insurance stratified based on a median EBAS.



Chapter 5

Discussion

This cross-sectional study assessed the relationships between the social and behavioral characteristics of individuals with type 2 diabetes and their level of glycemic control, and compared these relationships in those with insurance to those without insurance that covers SMBG testing strips. After reviewing the findings from this study and relating these findings to past research, the limitations of this study will be discussed. Finally, implications of the findings to practice, policy, and future research will be presented.

5.1.0 Correlates of Glycemic Control

5.1.1 SMBG and HbA1c

For the patients in this study, it was found that there was no relationship between self-reported frequency of BG monitoring and HbA1c. When the mean SDSCA blood glucose testing scores were stratified based on levels of blood glucose control, there was a small positive correlation ($r = 0.26$; $p = 0.028$) among those with an optimal level of BG control (i.e., HbA1c <7.0%). This suggests that among those in optimal blood glucose control, lower HbA1c values are associated with less frequent testing. With cross-sectional data, this may reflect less need to perform SMBG at this level of BG control. There were no relationships between HbA1c and mean SMBG scores in any of the other levels of BG control. After controlling for clinical, demographic, HRQOL and barriers to SMBG the relationship between HbA1c and SMBG remained small and non-significant.

When looking at the independent variables in the multivariate model of the SDSCA glucose score, there was one significant variable in the model. Self reported history of at least one episode of minor hypoglycemia in the last 3 months was a significant independent variable. While the overall model was not significant, the small positive coefficient would indicate that those with one or more events of minor hypoglycemia would test the blood glucose more frequently, according to their health care practitioner's advice.

Our data did not support Franciosi's (Franciosi et al., 2001) recent observation on the relationship between frequency of SMBG and HbA1c. Franciosi et al. evaluated 3,567 patients with type 2 diabetes in an outpatient setting. For subjects that were not on insulin (n=2,255), a higher frequency of SMBG was related to a higher HbA1c, suggesting that patients with poor metabolic control have a greater tendency to self-monitor. For subjects on insulin, more frequent SMBG was shown to be associated with better metabolic control in patients who were able to self-adjust insulin doses. Franciosi also explored the relationship between SMBG and metabolic control in a subgroup of patients who were not using insulin and whether the information obtained from SMBG could be readily utilized by the patient or the patient was not educated on the actions to be taken when their BG levels were high. There was no correlation between SMBG and better metabolic control in this group of patients.

Likewise, our data did not support Karter's (Karter et al., 2001) conclusion that more frequent SMBG was associated with clinically and statistically better glycemic control. In a sample of 24,312 adult patients with diabetes, those with non-pharmacologically treated type 2 diabetes that practiced SMBG, showed a 0.4% lower

HbA1c (p = 0.0001) compared to those that did not practice SMBG. For those with type 2 diabetes treated by oral agents only, those that were adherent to SMBG had a 0.6% (absolute) lower HbA1c (p = 0.0001) compared to those that were nonadherent to SMBG practices.

Harris and colleagues (Harris et al., 2001) also found a relationship between HbA1c and SMBG frequency, for both people with type 1 and type 2 diabetes. It was found that as HbA1c increases, SMBG is more common. However, this increase in monitoring was found to be related to the higher proportion of insulin treated patients, who are more likely to self-monitor in higher HbA1c categories. When patients were stratified based on treatment of diabetes, there were little or no relationship between frequency of SMBG and HbA1c.

Using the NHANES III data, Harris et al. showed that the great majority of patients treated with oral agents or diet alone monitored their blood glucose rarely, if at all (Harris et al., 2002; Kennedy, 2001). In fact, SMBG at least once per day was undertaken by only 5-6% of patients, while 80% of those on diet and 65% of those treated with oral agents reported having monitored either never or less than once per month. In our study sample, the self-reported frequency of those that tested greater than once per week was approximately 88%. In our sample, 28.1% of the patients in this study self-reported that they test their blood sugars on a daily basis, which has been higher than previous studies (Harris et al., 2001; Karter et al., 2001; Franciosi et al., 2001).

The literature on the relationship between SMBG on HbA1c has also been reviewed by Faas et al. (1997) and Coster et al. (2000). Of six randomized control studies identified by Faas, only one showed positive conclusions regarding the efficacy of

SMBG. Faas concluded that the efficacy of SMBG for those with type 2 diabetes is still questionable; however, Faas continued to recommend SMBG for those with poor glycemic control despite optimal antidiabetic therapy. Coster likewise showed, by meta-analysis of randomized control trials, that SMBG was not effective at improving blood glucose control in type 2 diabetes.

In addition to self-reported frequency of SMBG, we also assessed on how many days the patients tested according to their health care professional's recommendations. Approximately one-quarter of the respondents reported that every day for the last 7 days they tested according to their health care professional's recommendations. The relationship between the frequency of SMBG according to their health care professional in the last 7 days and HbA1c was likewise not significant ($r = -0.019$, $p=0.796$).

It was anticipated that some social desirability might be present when patients self-reported their frequency of SMBG practices. Social desirability was tested by running the analysis excluding those subjects that reported testing on a daily basis. The results from this analysis did not significantly change the direction nor the strength of the relationship between frequency of BG testing and HbA1c ($r = 0.003$; $p = 0.971$).

Fontbonne (Fontbonne et al., 1989) contemplated what kind of monitoring would help a poorly controlled non-insulin treated diabetic population to improve their metabolic control. Among insulin-treated patients, the benefit of SMBG for metabolic control seems to be restricted to those who are able to adjust their insulin doses, supporting the concept that glucose self-monitoring is effective when used for self-regulation (Franciosi et al., 2001, Gallichan et al., 1997). However, most patients with type 2 diabetes do not typically adjust their medications based on individual SMBG values. Rather, those with type 2 diabetes who are not on insulin interact with their health care provider to adjust medication based on a pattern of SMBG values. Optimal modern therapy of type 2 diabetes uses a "treat-to-target" approach, expeditiously moving patients along a sequence of therapies to achieve better diabetes control, reassessing each therapy at 2-4 month intervals if glucose goals are not achieved (Blonde et al., 2002; Meltzer et al., 1998).

If the patients in our study were indeed highly motivated to test their BG on a daily basis and they also adhered to the recommendations of SMBG that was prescribed to them by their health care practitioner, another issue is brought forward. This issue is how to differentiate between those that are merely self-monitors from those that are self-regulators? Self-regulators would be those patients who are active in their day-to-day diabetes self-management which includes the knowledge to adjust diet, exercise, and, in conjunction with their health care provider, the ability to adjust their therapeutic approaches. One explanation for the lack of association between SMBG frequency and HbA1c is that while patients may be testing their BG they are not using this information and therefore not making any adjustments to their therapeutic approaches.

Diabetes education has been recognized as an intervention that contributes to improved self-care, and thus improved control in diabetes (Guirguis et al., 2002; Tu et al., 1993; Rubin et al., 1989). Patient education is necessary because diabetes is serious, largely self-managed, and a personal responsibility (Funnell et al., 2002). However, it has been estimated that 50% to 80% of people diagnosed with diabetes lack significant knowledge and skills to manage the condition effectively (Raji et al., 2002). Supporting the above figure, the Canadian Diabetes Association estimates that 70% of people with type 2 diabetes do not receive appropriate diabetes self-care education (Haanstra & Mayer, 1998). In order for patients to be self-regulators, there is a need for enhanced diabetes education.

Educational programs that have been found to be successful have used a combined approach (Ozmen at al., 2002, Funnell et al., 2002) that included training health care providers, adjustment of medication doses, and frequently reinforcing educational messages (Ozmen at al., 2002). Norris et al (2001) found that interventions that included more interaction and collaboration with the patient were more effective. Educational programs alone are not enough to decrease HbA1c levels (Ozmenet al., 2002) but it forms the framework on which medications, nutrition, and other lifestyle modifications are built (Raji et al., 2002).

Intervention research which includes SMBG in type 2 diabetes has almost exclusively focused on behavioral weight loss programs (Gonder-Frederick et al., 2002; Coster et al., 2000; Fass et al., 1997). As emphasized by both Muchmore et al. (1994) and Wing et al. (1986), it is essential to link SMBG results to a specific behavioral response in order to demonstrate the potential efficacy of SMBG as a management method. If 28% of our patients are performing SMBG on a daily basis, further studies would be required to assess the relationship of SMBG with other self-care activities, whether it was exercise, diet, or medication adjustment.

One other explanation for the lack of association between HbA1c and frequency of SMBG in our study is the duration of diabetes of our patients. Patients with type 2 diabetes are often required to adopt increasingly stringent and complicated control strategies, often culminating in the need for insulin treatment (Muchmore et al., 1994). It may be unlikely that we would see a relation between HbA1c and frequency of monitoring for those patients that have been diagnosed with DM for greater than 6 years and who are not on insulin. Wright and coworkers (Wright el al., 2002) found that 53% of patients with newly diagnosed type 2 diabetes treated with sulfonylurea therapy required the addition of insulin to their treatment within 6 years of diagnosis to maintain FBG levels <6.0mmol/L. This might apply not just to sulfonylurea but also to metformin and thiazolidinediones (Riddle MC, 2002).

In our study, just over one-half (51.8%) of our sample was diagnosed with DM ≥6 years ago. Similar to the UKPDS (Wright et al., 2002), 51.5% of our patients that were diagnosed with diabetes ≥6 years ago also had a suboptimal (i.e., 7.0% -8.4%) or inadequate (i.e., > 8.4%) HbA1c. With our patients, there was a significant difference in HbA1c between those who were diagnosed <6 years ago (6.89%) and those that were diagnosed ≥6 years ago (7.43%; $p = 0.01$). If our patients were self-regulators, then in theory half of the patients in our study would not be able to reach optimal HbA1c without the addition of insulin to their therapy.

5.1.2 Fear of hypoglycemia

There were no significant correlations between fear of hypoglycemia and glycemic control overall or when patients were stratified by level of blood glucose control. In multivariate analysis, after adjusting for clinical, demographic and insurance that covers SMBG test strips, there was still no relationship between hypoglycemia fear and glycemic control.

In previous studies, the mean scores for the worry subscale of the HFS for those with type 2 diabetes and on insulin range from 28.3 (SD 9.9) to 37.0 (SD 16.0) (Cox et al., 1987; Irvine et al., 1992; Polonsky et al., 1992) with the mean behavioral subscales ranging from 25.0 (SD 8.0) to 26.5 (SD 6.6). In comparison, our reported mean scores for this study were lower at 19.3 (SD 9.6) and 17.0 (6.9) for the worry and behavioral subscales, respectively, suggesting that our subjects, who were not on insulin, had less fear of hypoglycemia than those people with type 2 diabetes on insulin.

Mild hypoglycemia is common in patients with type 2 diabetes undergoing aggressive diabetes management, but severe hypoglycemia is rare (Miller et al., 2001). Rates of severe hypoglycemia in those treated with sulfonylureas or in combination with other oral agents have been reported in the range of 0.5% to 1.4% (Miller et al., 2001; Chan, 1998; vanStaa et al., 1997). In the UKPDS, one or more episodes of hypoglycemia were reported at 1.4 – 5.4% per annum depending on treatment allocation (UKPDS, 1998). In comparison, the DCCT reported rates for hypoglycemia requiring assistance at 6.1% per annum in the intensive treatment group versus 1.9% in the conventional treatment group; for hypoglycemia involving coma or seizure, the rate was 1.6% vs. 0.5% (DCCT, 1995).

For our study, we defined minor hypoglycemia as experiencing low blood sugars that the patient was able to treat by themselves. Less than half of our patients reported one or more events of minor hypoglycemia in a three month period. Severe hypoglycemia was defined in our study as an event of low blood sugars that required help by another person or going to the hospital to be treated over the preceding three month period. Eight subjects (4.0%) in our study reported one or more severe hypoglycemia events over a three month period.

Previous research suggests that aggressive management aimed at achieving near-normal glucose levels in patients with type 2 diabetes is associated with increased risk of hypoglycemia as HbA1c levels approached less than 7.0% (Miller et al., 2001). When we stratified patients based on levels of blood glucose control, there were no significant correlations between fear of hypoglycemia and glycemic control. There were no significant differences in the HFS subscales and the overall measurement for between those patients with an HbA1c ≤ 7.0% and those with an HbA1c >7.0%.

According to the developer of the HFS, if hypoglycemia is not a potentially common event, then the responses to the HFS reflect more neuroticism than fear of a potential reality (Cox, 2001). The UKPDS (UKPDS, 1999) supports Cox's statement and may offer some insight into the lack of relationship between fear of hypoglycemia and glycemic control, despite 42% of our patients reporting minor hypoglycemia. The UKPDS concluded that patients with certain personality traits or many symptoms also reported increased numbers of hypoglycemic attacks (UKPDS, 1999).

5.1.3 Health Related Quality of Life

This study demonstrated no relationships between mental (MHS) or physical (PHS) health status and HbA1c at any level of BG control. When these variables were explored in the multivariate analysis, the overall models were not significant; however, there were two variables that were significant in the PHS multivariate model. Insurance for SMBG test strips was the first variable that was significant in the model ($\beta = -1.026$; $p<0.005$). The interaction term between PHS and insurance was also significant ($\beta = 0.96$; $p<0.01$). The significant interaction term indicates that the relationship between HbA1c and PHS varies according to the patients' insurance for diabetes testing supplies.

Generic measures, while useful for comparing across disease states, often fail to demonstrate an association between HRQOL and HbA1c (Maddigan et al., 2002). Similarly, other studies have reported that therapies to improve glucose control do not affect HRQOL measured by generic measures (UKPDS, 1999; Glasgow et al., 1997). The lack of a relationship between health status and HbA1c should not be surprising, however, given the complex relationships between self-management, diabetes control and HRQOL (Gonder-Frederich et al., 2002).

Research into using the RAND-12 to study HRQOL in diabetes has been limited, but recent evidence suggest it is a valid assessment of health status in type 2 diabetes (Maddigan et al., 2002; Johnson & Maddigan, forthcoming). In this recent work (Johnson & Maddigan, forthcoming), the PHS and MHS of the RAND-12 discriminated between individuals anticipated to have differing levels of disease severity or advancement, for a number of comparisons. Similar to our study, there were no relationships found between PHS and MHS of the RAND-12 and HbA1c. In comparison, our subjects' have slightly higher mean PHS and MHS scores at 44.93 (SD 10.40) and 47.38 (SD 9.38) respectively, but these values were still within one standard deviation of Maddigan et al. When compared to United States population norm (Hays, 1998), the PHS scores were over one-half standard deviation below the norm of 50, while the MHS scores were slightly below the population norm.

In the UKPDS, presence of diabetes complications was associated with lower HRQOL, but there was no association between HbA1c and HRQOL, symptoms, mood, or general well-being (UKPDS, 1999). One of the limitations cited in the UKPDS HRQOL study, which was a cross-sectional study, was a narrow distribution of HbA1c for both the specific and generic HRQOL questionnaire being studied (7.9%; SD 1.8 and 8.1%; SD1.7). Our study supports the finding of no association of HbA1c with HRQOL with a similar distribution of HbA1c (mean 7.2; SD 1.17). It may be that HRQOL would be associated with glycemic control over a wider distribution of HbA1c.

In contrast to these studies, Testa observed a strong relationship between improved glycemic control and beneficial changes in HRQOL (Testa et al., 1998). However, the HRQOL measures that were used by Testa were of unknown validity and reliability and could have possibly examined different domains. Likewise, Klein et al. (1998) also reported HbA1c as a significant predictor in two of the eight SF-36 scales. HbA1c was negatively associated with general health, and the single self-related health question when placed into a multiple linear regression analyses that included complications of diabetes, age and other characteristics. In comparison, we did not find an association between the single self-rated health question and HbA1c ($r = 0.12$; $p = 0.094$).

Gonder-Frederich et al. (2002) support the need to consider HRQOL and diabetes control as separate outcome measures. Likewise, Ibrahim (2002) hypothesized that other factors, in addition to clinical indicators, play a role in HRQOL. Perhaps burden of managing disease, complications, co-morbidities and barriers to care are more relevant measures of HRQOL in diabetes than HbA1c. Cardiovascular disease in diabetes mellitus has been shown to have a negative effect on quality of life (de Visser, 2002;

UKPDS, 1999). Likewise, microvascular complications have been shown to contribute to a decreased HRQOL (UKPDS, 1999). A study by Watkins (2000) showed that dietary adherence may negatively affect quality of life by increasing the level of perceived diabetes burden. Restrictions or perceived barriers may negatively affect individuals' perceptions of life quality and interactions with others. Patients in this study had a small negative relationship between barriers to adherence of SMBG and both PHS and MHS (-0.185 and -0.164 respectively; $p<0.05$).

Nonetheless, HbA1c remains an important clinical outcome as the primary indicator of glycemic control. As an intermediate outcome HbA1c is clearly associated with the development of microvascular outcomes. It is appropriate therefore to assume that reductions in HbA1c will lead to reductions in microvascular complications. The relationship between HbA1c and macrovascular complications and how people feel (i.e. HRQOL) is not clear, however, so these outcomes should be assessed independently. Stated another way, if the goal of treatment is to make people feel better then it is important to obtain direct measurements of self-reported HRQOL.

5.1.4 Environmental Barriers to Adherence to SMBG

When we evaluated the relationship between barriers to SMBG, as measured by EBAS, and HbA1c, we found no significant relationship. After controlling for potential confounding by clinical, demographic and HRQOL variables, the relationship was still not significant.

The mean overall EBAS score was 20.5 (SD 7.5), indicating that patients reported never, or rarely, having barriers to SMBG as listed by the questionnaire. When we further explored cost as a barrier to SMBG, however, we found that there was a significant difference in responses between those with insurance that covers SMBG testing strip and those without insurance that covers SMBG testing strips. Those with insurance more frequently indicated that cost was never, or rarely, a barrier to SMBG compared to those without insurance.

These findings are supported by Karter (2001) who observed that SMBG practice patterns may be sensitive to out-of-pocket expenditures for SMBG testing strips, especially for those with lower incomes. This study was done in a large managed care organization in which patients presumably have similar access to care. Likewise, Nyomba et al. (2002) found that patients who were given free SMBG test strips had lower HbA1c and average blood glucose and insulin doses versus control subjects who didn't receive free test strips.

An explanation for patients perceiving low barriers to SMBG could be that they do not perceive SMBG as having any effect on treatment effectiveness (Glasgow et al., 1997). Also, the barrier scale assessed the frequency of different barriers, but not the level of difficulty posed by each barrier (Glasgow et al., 1997). A frequent barrier may interfere with SMBG testing only if it is perceived as difficult. However, the opposite of the above explanations could also be true. Patients might feel that SMBG is effective in their diabetes management, and in turn, may feel that the benefit of SMBG outweighs any perceived barrier.

5.1.5 Insurance for SMBG Test Strips

Interestingly, while in our study there were no relationships between HbA1c and the overall EBAS or the individual question of cost as a barrier to SMBG, there was a clinically significant difference in HbA1c (0.37%; $p<0.05$) between those who had insurance that covered BG testing strips and those who did not. Those with insurance that covers SMBG test strips were significantly younger compared to those without insurance for SMBG test strips. We did not find any differences in duration of diabetes based on insurance coverage. From the differences in ages we might hypothesize that those with insurance are of a younger group who have private coverage through employers, that covers SMBG test strips. In Alberta, the public senior drug plan does not cover SMBG test strips.

The largest differences in HbA1c were with subjects who had inadequate control of there blood sugars (i.e. HbA1c >8.4%). Those with insurance coverage had a HbA1c 0.5% ($p=0.301$) lower than those without insurance. While statistically the difference is not significant, this study was not powered to look at the small number of subjects in this subgroup ($n=25$). When physical health and glycemic control was explored, subjects with poorer physical health and without insurance coverage had the poorest glycemic control even when age was controlled. Poor physical health may result in inability to access adequate care from health professionals or the inability to exercise, either lead to poorer glycemic control.

5.2 Research Limitations

Due to the cross-sectional and correlational design of this study, no inferences of causality can be drawn. Therefore, it cannot be determined from this study whether self-monitoring frequency causally influences blood glucose control. With this in mind, all relationships described in this study are associations between the variables of interest. Additionally, any changes in HbA1c cannot be observed. Subjects, through self-report, recorded on how many of the last seven days they preformed SMBG. Any changes in monitoring that may have occurred in the previous weeks would not have sufficient time to impact their HbA1c; which measures glycemic control over the last 3-4 months. Prospective studies with random allocation of SMBG supplies would be required to draw conclusions on causality and address any changes in HbA1c.

The study was sufficiently powered to detect the hypothesized relationships with all the subjects collapsed into one level of glucose control. We did look at the hypotheses with subjects stratified based on the clinical practice guideline's levels of glucose control, however there was insufficient power to detect significant correlations. The intent of looking at the various levels of blood glucose control was to merely explore the relationships at those levels of control. Individual levels of blood glucose control can be analyzed with full recruitment in the randomized control study.

When comparing the absolute HbA1c values in the sample of 10 patients with the two different laboratory methodologies, the ICC value was 0.77. The mean difference in HbA1c between the two methodologies was 0.26% (SD = 0.26). The majority (90%) of the differences in the HbA1c values between the two different methodologies was in the same direction. When the ICC was calculated based on stratification into levels of blood glucose, the ICC was 0.90. For the purposes of this cross-sectional correlational study, the difference between the two methodologies was acceptable.

The study used self-report instruments to measure frequency of blood glucose testing, insurance status, HRQOL, fear of hypoglycemia, and to collect other clinical and demographic information. Factors such as social desirability and memory could have affected the results (Aljasem, 2001). Social desirability in self-reported frequency of SMBG was addressed in this study by re-running the analyses excluding those that responded to test seven out of seven days. We found that there were no significant differences in the strengths or relationships of the correlations when we controlled for social desirability. A longitudinal study that utilized SMBG meter memories would enable a researcher to address the patients' memory when gathering information about frequency of SMBG.

The limitation of using a generic measure of HRQOL, the RAND-12, as the only HRQOL measure was addressed in the methods chapter of this thesis. To summarize, the use of the RAND-12 in this study was justified by the context of which the study was carried out. In order to assist in the decision-making process in assessing the provision of free testing supplies in the randomized control study, generic measures would be required. Relationships between HRQOL and HbA1c may have been detected with disease specific measurement; however, addition of disease specific measurement would increase response burden. Increased response burden would be a concern in this study as subjects completed the questionnaires on their own time without any incentives.

This study used volunteers that were recruited in a network of community pharmacies. These volunteers are more likely to be compliant to recommended self-management activities. This would result in a more homogeneous sample that made it more difficult to find correlations in the stated hypotheses.

Nonparticipants, whose' clinical, demographic, and SMBG practices may vary from the participants, were not captured and affects the generalizability of the study. Those of native/aboriginal ancestry were excluded from this study despite the higher prevalence of diabetes in this group (Benyshek et al., 2001). However, this population has full coverage for SMBG testing strips and therefore would have been generally excluded from this study regardless.

5.3 Practice Implications

There are no recommendations on frequency of SMBG made in the current CDA-CPG and the ADA CPG for those persons with type 2 diabetes and who are not on insulin. While this study does not contribute in establishing a definitive answer of optimal frequency of testing, this research offers insight into the behaviors of SMBG practices in people with type 2 diabetes who are not on insulin.

The major finding of this study is that frequency of SMBG does not correlate with HbA1c. While the causality cannot be inferred, a potential practice implication of this statement is that while a patient may be diligent in testing their blood sugars on a regular basis, without the proper self-management behaviors they do not necessarily have any benefit, in terms of glycemic control. Both patient and physician action are needed to change diabetes management when hypoglycemia or hyperglycemia is evident (Harris et al., 2001). To make effective and efficient decisions about therapy, patients and health care professional need to rely on appropriate data, of which SMBG is a key component (Blonde et al., 2002).

Health care providers should encourage people to test their blood sugars in order to collect the necessary information required to make changes the patient's self-management regime. Health care providers should also ensure that patients understand the purpose of SMBG. This includes educating the patients on when to test, how to interpret values, and most importantly what actions to take with the results. Without the ability to properly act on the results, SMBG may be a wasted resource.

Identifying and working with patients in poorer physical health, with limited financial access to SMBG supplies, should be a priority for health care professionals' diabetes management strategies. From this study it could be hypothesized that decreasing the financial barriers to SMBG resources may not be the only answer in this group of patients. An improvement on this strategy would be optimizing the information on glycemic control obtained from SMBG resources that is available to these patients and incorporating this information into enhanced diabetes self-care management.

In the overall assessment of patients; measurement of glycemic control, while important, does not tell you how people are feeling. This is not to say that HRQOL and optimal glycemic control are incompatible clinical goals (Weinberger et al., 1994), rather this study supports that these two desirable outcomes may not be directly related. In any case, the fact that these two variables are uncorrelated may help to explain the difficulty that some patients have in achieving good glycemic control. Because control is not correlated with HRQOL, patients may be unwilling to follow complex and intrusive regimens that do not appear to improve their health status. Patients who perceive benefits to improved glycemic control other then short term HRQOL may be more successful in their diabetes self-management.

5.4 Policy Implications

Increasingly, providers, payers, policymakers, and purchasers of care recognize diabetes as one of the most prevalent and expensive healthcare problems (Funnell & Anderson, 2002). Accessibility and costs of SMBG testing supplies remains a serious area of concern for Canadian provincial and territorial governments (CDA, 2001). Many provincial governments are currently deciding on whether diabetes testing supplies should be a covered benefit in the provincial health plans.

In the four western provinces alone, there is considerable variation in coverage for diabetes testing supplies (CDA, 2001). British Columbia has a deductible and co-pay system in place that covers test strips, if a patient attends an annual periodic certification program. Alberta's program covers 65% of the cost of SMBG supplies to a yearly maximum of $350 for those on insulin and have no other insurance that covers the supplies. Residents in Saskatchewan have blood glucose test strips covered under the Saskatchewan Prescription Drug Plan, which employs a co-pay and deductible mechanism, based on gross income. Manitoba has taken the approach to limiting the quantity of strips to 4,000 per benefit year.

Subjects without insurance for SMBG test strips reported in our study greater financial barriers to SMBG and had poorer glycemic control. For some subjects, provision of free SMBG test strips would facilitate management of their disease; with the results of monitoring providing valuable information on efficacy of their diabetes self care activities. In this study, the most vulnerable patients that are without insurance and in poorest physical health, regardless of age, had the poorest glycemic control. This implies that public insurance for strips that targets only older patients may not be the most efficient.

However, while access to free SMBG testing supplies would facilitate patients and care providers in gathering the appropriate information, management of therapy would remain a serious area of concern. There is some evidence that testing as part of standardized extensive diabetes education programs can make a difference (Guirguis et al., 2002). Within our healthcare system, however, resources available for continuity of care and consistent follow-up required for those individuals with diabetes are a concern.

One scenario that policy makers may consider is tying two aspects of diabetes management together; coverage of SMBG testing supplies and ongoing diabetes education. British Colombia ties the two aspects of diabetes self-management together in an unique system for coverage of strips by the provincial Pharmacare program. The Ministry of Health Services employs a monitoring certification program that is intended to promote effective self-care. As an incentive to encourage people with diabetes to access education, coverage of strips is tied into annual education in a Diabetes Education Centre. While there is a wide agreement in the Ministry that diabetes education is essential, patients have requested that the periodic certification requirement for coverage of test strips needs to be reconsidered. The Ministry is reviewing these policies and programs to assess how best to support diabetes education (CDA, 2002).

5.5 Future Research

In order to make an informed decision on recommendation for SMBG, and insurance coverage for SMBG test strips to those with type 2 diabetes and who are not on insulin, more research would be required. RCT trials looking at providing free SMBG strips to this population would present valuable information on the simple strategy of supplying free SMBG supplies and its effect on clinical and behavioral outcomes.

Future research projects could look at the impact of enhanced pharmacy practice, including adjustment of oral/insulin medications in type 2 diabetes based on SMBG values. These randomized clinical trials of enhanced pharmacy practice should have pre-established guidelines for how glucose monitoring results would be used to facilitate achievement of glycemic targets (Harris et al., 2001). The rational for the use of community pharmacies is that for the majority of patients with diabetes this is the point of care where they purchase their medication and testing supplies. Another rationale for using community based pharmacies is that they are ideally positioned in the community to interact with patients and facilitate self-management behaviors (Guirguis et al., 2001). Recent research on the provision of free testing supplies, for example, have been conducted through educational clinical in academic centres (Nyomba, 2002) thereby limiting the generalizability.

One of the obstacles to implementation of diabetes self-management is that our current health system is not designed to provide the continuity of care and consistent follow-up required by those with diabetes. Therefore, there is also an urgent need for more research into health care provider and health care delivery factors that enhance self-management behavior (Glasgow et al., 2001).

5.6 Conclusions

Overall, this cross-sectional study demonstrated little relationship between glycemic control and social or behavioural characteristics of people with type 2 diabetes. Self-reported frequency of SMBG was not associated with Hba1c at any level of glycemic control.

Despite a high (42%) self-reported frequency of minor hypoglycemia, there were no significant correlations between the fear of hypoglycemia and HbA1c. We also found that HRQOL, as measured by the RAND-12, does not correlate with HbA1c, suggesting that other factors such as co-morbidities reflect on HRQOL.

For patients in our study, environmental barriers, measured by the EBAS were rarely encountered. Patients without insurance for SMBG test strips did report cost of test strips as a greater barrier as compared to those with insurance that covered the test strips. It is interesting to note that while many patients without insurance feel that cost of SMBG strips is rarely, to sometimes, a barrier to testing, there was a clinically significant difference in HbA1c in contrast to those that do have insurance for SMBG test strips.

Further research into SMBG would be required in order to make informed policy decisions. With provincial ministries experiencing ever-increasing pressures on their drug budgets, expansion for coverage of SMBG test supplies should take into consideration the impact that SMBG has on diabetes self-management activities and clinical outcomes.

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Appendix 1

Study Information Letter and Consent Form

Study of Testing Response In Patients with Type 2 Diabetes (STRIP-Type2) PART 1

Principal Investigator:	**Department / Program***	**Telephone**
Jeffrey A. Johnson	Department of Public Health Sciences, UofA	(780) 448-4881
Co-Investigators:		
Ellen L Toth	Division of Endocrinology & Metabolism, UofA	(780) 407-6223
Sumit R. Majumdar	Division of General Internal Medicine, UofA	(780) 407-7555

Purpose

You are being asked to take part in a research study. The aim of this study is to find out the link between how you feel, the things you do to look after your diabetes, and your blood sugar control.

Procedures

You will be asked to fill out a 20-minute survey and give a blood sample at a lab. The survey will tell us about you, what you do to look after your diabetes, your ability to do things on a day to day basis, and how you feel about your health. The blood sample will tell us about your blood sugars.

Based on the results of your blood sample, you may be phoned and asked to be involved in Part 2 of this study. Part 2 will find out if giving blood sugar meters to people with diabetes helps their blood sugar control. If you are asked to take part in Part 2 we will provide you with more information at that time.

Risks and Benefits

There are no known risks in this study. By taking part in this study you may have the chance to learn more about your diabetes. Another benefit is that you will be helpful in finding out the links between blood sugars, how you feel, and what you do to look after your diabetes.

Privacy

All information will be held private except when professional codes of ethics or the law require reporting. The information you provide will be stored for at least 5 year after the study is done. The information will be kept in a locked filing cabinet in a secure area at the University of Alberta. Your name will not be attached to any information you give. Your name will never be used in presentations or report of the study results.

Personal records relating to the study will be kept private and will only be read by the research team. The only person who knows you are taking part in this study and will contact you is your pharmacist at Shopper's Drug Mart. Your doctor, pharmacist, and other health care providers will not see any surveys you fill in.

Freedom to Withdraw

We would truly value your participation in this study. However, you are free to refuse to take part in the study. You are also free to not answer any of the questions if you don't want to. If, for any reason, you want to stop being in this study, you are free to stop at any time. In either case, your usual level of care will not change in any way.

Contacts

If you have questions about any part of this study, please call your local coordinator Chad Mitchell at 448 - 4881 or the lead researcher Dr. Jeff Johnson at (780) 448-4881.

If you have any concerns about the study, please contact Dr. Sharon Warren, Chair of the ethics board at (780) 492-0839.

Thank you very much for your interest in this study.

Study of Testing Response In Patients with Type 2 Diabetes
(STRIP-Type2) Part 1

Principal Investigator:	**Department / Program***	**Telephone**
Jeffrey A. Johnson	Department of Public Health Sciences	(780) 448-4881
Co-Investigators:		
Ellen L Toth	Division of Endocrinology & Metabolism	(780) 407-6223
Sumit R. Majumdar	Division of General Internal Medicine	(780) 407-7555

To be completed by the research subject:

Do you understand that you have been asked to be in a research study?	Yes	No
Have you read and received a copy of the attached Information Sheet?	Yes	No
Do you understand the benefits and risks involved in taking part in this research study?	Yes	No
Have you had an opportunity to ask questions and discuss this study?	Yes	No
Do you understand that you are free to refuse to participate or withdraw from the study at any time? You do not have to give a reason and it will not affect your care.	Yes	No
Has the issue of confidentiality been explained to you?	Yes	No
Do you understand who will have access to your records?	Yes	No

This study was explained to me by: ______________________ Date:__________

I agree to take part in this study.

Signature of Research Subject______________________________ Witness

Printed Name

Printed Name

To be completed by the Study Pharmacist:

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

____

Study Pharmacist

____

Date

Appendix 2

Questionnaire

STRIP-Type2

Study of Testing Response In Patients
with Type 2 Diabetes

Patient Initials: ☐☐☐ **Study ID Number:** ☐☐☐☐☐☐

This survey asks you about your health and the health care services that you receive.

Please check the answer that best describes your opinion. There are no right or wrong answers; what we want is your opinion. All information you provide is confidential.

Some questions may not apply to you but it is important that we ask the same questions of everyone. If you are unsure about how to answer, please give the best answer you can. You may leave answers blank if you object to the question being asked.

If you have any questions about this study or the questionnaire contact your local study coordinator Chad Mitchell at (780) 448 - 4881.

When you have completed the questionnaire, please return it in the self-addressed envelope that is provided.

STRIP-Type2 Study

PART 1

The next 9 questions will ask you for important information about you and your household. For each of the questions below, please indicate your answer by checking the ONE response that best describes your answer (except where noted). Place an "X" or " ✓ " on the line in front of the answer.

☐☐☐☐

1. What is your year of birth?

2. What is your sex? ____ Male

____ Female

3. What is your current marital status? (***Mark ONE only***)

___ Now married
___ Common-law
___ Living with a partner
___ Single (never married)
___ Widowed
___ Separated
___ Divorced

4. Is English your first language? (***Mark ONE only***)

___ Yes
___ No

5. Do you speak any other languages (fluently)?
(Check as many as apply)

___ English
___ First Nations

STRIP-Type2 Study

6. Are you Aboriginal, First Nations, or Hispanic?
(Mark ONE only)

___ Yes
___ No

7. Have you graduated from high school?
(Mark ONE only)

___ Yes
___ No

8. What do you consider to be your current main activity?
(***Mark ONE only***)

___ Caring for family
___ Working for pay or profit
___ Caring for family and working for pay or profit

___ Going to school
___ Recovering from illness/on disability
___ Looking for work
___ Retired
___ Other (Specify ______________________)

9. What is your best estimate of the total income before taxes and deductions of ALL household members from all sources in the past 12 months? Was the total income: (***Mark ONE only***)

___ less than $5,000
___ $5,000 to $19,999
___ $20,000 to $39,999
___ $40,000 to $59,999
___ $60,000 to $79,999
___ $80,000 or more

STRIP-Type2 Study

Part 2

The next 14 questions will ask you for important information about your diabetes and your health. For each of the questions below, please indicate your answer by checking the ONE response that best describes your answer (except where noted).

10. *How long have you had diabetes?* _______ *years*

11. Has a health care provider ever told you that you have high blood pressure? (***Mark ONE only***)

___ Yes
___ No

12. Has a health care provider ever told you that you have high cholesterol? (***Mark ONE only***)

___ Yes
___ No

13. What is your current weight in pounds?

_______ pounds

14. What is your current height in feet and inches?

______feet and _______inches

15. How may times have you seen a doctor **in the last six month**?

________times

16. How may times have you seen a doctor **for diabetes in the last six month**?

STRIP-Type2 Study

17. Have you ever been to a diabetes education clinic?
(***Mark ONE only***)

___ Yes
___ No

18. *If yes, when did you last attend diabetes education clinic?* _____*years ago*

19. Have you ever used a blood glucose meter before?
(***Mark ONE only***)

___ Yes
___ No

20. Do you currently have a blood glucose meter?
(***Mark ONE only***)

___ Yes
___ No

21. If yes, how many blood glucose meters do you have?

________ meters

STRIP-Type2 Study

22. Do you have any of the following medical conditions **due to your diabetes?**

Vision problems ___ Yes
___ No

Cataracts ___ Yes
___ No

Kidney Disease ___ Yes
___ No

Foot Problems ___ Yes
___ No

Amputations ___ Yes
___ No

Nerve Disease ___ Yes
___ No

23. In the last 3 months, have you experienced low blood sugars that:

You were able to treat yourself without help?
___ Yes
___ No

You needed help by another person or you went to the hospital to treat?
___ Yes
___ No

Environmental Barriers to Adherence Scale

For the following questions, circle the correct letter. Please do not skip any questions.

N = never
R = rarely
S = sometimes
O = often
A = always
NA = not applicable

To what extent does each of the following keep you from testing your blood sugar as you think you should?

	N never	R rarely	S sometimes	O often	A always	NA not applicable
1. Finding the time at home	N	R	S	O	A	NA
2. Finding the time at work	N	R	S	O	A	NA
3. Finding a good place	N	R	S	O	A	NA
4. The inconvenience (of carrying my materials)	N	R	S	O	A	NA
5. Problems with my health (trouble seeing, etc.)	N	R	S	O	A	NA
6. Forgetting to test	N	R	S	O	A	NA
7. Feeling sick	N	R	S	O	A	NA
8. It's too complicated	N	R	S	O	A	NA
9. It's too painful	N	R	S	O	A	NA
10. Being away from home (shopping, traveling, etc.)	N	R	S	O	A	NA
11. Changes in my schedule (sleeping late, working late, etc.)	N	R	S	O	A	NA
12. The cost of supplies	N	R	S	O	A	NA
13. Special occasions (holidays, etc.)	N	R	S	O	A	NA

During the past week, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

		Yes	No
6.	**Accomplished less** than you would like	☐	☐
7.	Didn't do work or other activities as **carefully** as usual	☐	☐

8. During the past week, how much did pain interfere with your normal work (including both work outside the home and housework)?

☐	☐	☐	☐	☐
Not at all	**A little bit**	**Moderately**	**Quite a bit**	**Extremely**

These questions are about how you feel and how things have been with you during the past week. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past week -

		All of the Time	**Most of the Time**	**A Good Bit of the Time**	**Some of the Time**	**A Little of the Time**	**None of the Time**
9.	Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
10.	Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
11.	Have you felt downhearted and blue?	☐	☐	☐	☐	☐	☐

12. During the past week, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

☐ ☐	☐	☐	☐	
All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**

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PART 3

SF-12 Health Survey

INSTRUCTIONS: This questionnaire asks for your views about your health. This information will help keep track of how you feel and how well you are able to do you usual activities.

Please answer every question by marking one box. If you are unsure about how to answer, please give the best answer you can.

1. In general, would you say your health is:

☐	☐	☐	☐	☐
Excellent	**Very good**	**Good**	**Fair**	**Poor**

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

		Yes, Limited A Lot	Yes, Limited A Little	No, Not Limited At All
2.	**Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐	☐	☐
3.	Climbing **several** flights of stairs	☐	☐	☐

During the past week, have you had any of the following problems with your work or other regular daily activities as a result of you physical health?

		Yes	No
4.	**Accomplished less** than you would like	☐	☐
5.	Were limited in the **kind** of work or other activities	☐	☐

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Blood Sugar Testing

7. On how many of the last SEVEN DAYS did you test your blood sugar?

0 1 2 3 4 5 6 7

8. On how many of the last SEVEN DAYS did you test your blood sugar the number of times recommended by your health care provider?

0 1 2 3 4 5 6 7

Foot Care

9. On how many of the last SEVEN DAYS did you check your feet?

0 1 2 3 4 5 6 7

10. On how many of the last SEVEN DAYS did you inspect the inside of your shoes?

0 1 2 3 4 5 6 7

Smoking

11. Have you smoked a cigarette – even one puff during the past SEVEN DAYS? (Please circle the answer that applies to you)

0 No

1 Yes. If *yes*, how many cigarettes did you smoke on an average day?

Number of cigarettes:______________

SDSCA Toobert et al., 2000 *Please proceed to next page +*

The Summary of Diabetes Self-Care Activities

The questions below ask you about your diabetes self-care activities during the past 7 days. If you were sick during the past 7 days, please think back to the last 7 days that you were not sick.

DIET

1. How many of the last SEVEN DAYS have you followed a healthful eating plan?

   0 1 2 3 4 5 6 7

2. On average, over the past month, how many DAYS PER WEEK have you followed your eating plan?

   0 1 2 3 4 5 6 7

3. On how many of the last SEVEN DAYS did you eat five or more servings of fruits and vegetables?

   0 1 2 3 4 5 6 7

4. On how many of the last SEVEN DAYS did you eat high fat foods such as red meat or full-fat dairy products?

   0 1 2 3 4 5 6 7

Exercise

5. On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? (Total minutes of continuous activity, including walking).

   0 1 2 3 4 5 6 7

6. On how many of the last SEVEN DAYS did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work?

   0 1 2 3 4 5 6 7

SDSCA Toobert et al., 2000 *Please proceed to next page +*

II. Worry: Below is a list of concerns people with diabetes sometimes have. Please read each item carefully (do not skip any). Circle one of the numbers to the right that best describes how often you WORRY about each item because of low blood sugar.

	Never	Rarely	Sometimes	Often	Always
I worry about....					
11. Not recognizing/realizing I am having low blood sugar	0	1	2	3	4
12. Not having food, fruit, or juice with me	0	1	2	3	4
13. Passing out in public	0	1	2	3	4
14. Embarrassing myself or my friends in a social situation	0	1	2	3	4
15. Having a reaction while alone	0	1	2	3	4
16. Appearing stupid or drunk	0	1	2	3	4
17. Losing control	0	1	2	3	4
18. No one being around to help me during a reaction	0	1	2	3	4
19. Having a reaction while driving	0	1	2	3	4
20. Making a mistake or having an accident	0	1	2	3	4
21. Getting a bad evaluation or being criticized	0	1	2	3	4
22. Difficulty thinking clearly when responsible for others	0	1	2	3	4
23. Feeling lightheaded or dizzy	0	1	2	3	4

HFS Cox et al., 1987

***Please** proceed **to next page** +*

Hypoglycemic Fear Survey

I. Behavior: Below is a list of things people with diabetes do in order to avoid low blood sugar. Read each item carefully. Circle one of the numbers to the right that best describes what you do during your daily routine to AVOID low blood sugar.

	Never	Rarely	Sometimes	Often	Always
1. Eat large snacks at bedtime	0	1	2	3	4
2. Avoid being alone when my sugar is likely to be low	0	1	2	3	4
3. If test blood glucose, run a little high to be on the safe side	0	1	2	3	4
4. Keep my sugar high when I will be alone for awhile	0	1	2	3	4
5. Eat something as soon as I feel the first sign of low blood sugar	0	1	2	3	4
6. Reduce my insulin when I think my sugar is low	0	1	2	3	4
7. Keep my sugar high when I plan to be in a long meeting or at a party	0	1	2	3	4
8. Carry fast-acting sugar with me	0	1	2	3	4
9. Avoid exercise when I think my sugar is low	0	1	2	3	4
10. Check my sugar often when I plan to be in a long meeting or out to a party	0	1	2	3	4

HFS Cox et al., 1987

Please proceed to next page +